Adverse events associated with chemotherapy in a cancer centre in a developing country

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ABSTRACT

Extensive international evidence has shown that a considerable number of patients are harmed by medication errors every year. This is the first study to investigate medication errors within cancer services in Sudan.

The first aim of this study was to investigate patient safety culture in a large cancer centre in Khartoum, Sudan. Focus groups using the MaPSaF were conducted with staff from the medical, nursing and pharmacy teams. The findings revealed lack of knowledge regarding patient safety systems among research participant. Participants implied that the study hospital has a low priority for patient safety.

The second aim of the study was to investigate the frequency, nature and potential causes of prescribing errors associated with chemotherapy. A mixed methods study was designed, composed of a quantitative prescription analysis followed by Critical Incident interviews and focus groups. During the study period, 10% of prescriptions contained at least one error, of which, nearly 90% of which had the potential to cause serious and life threatening harm. Errors were more likely with prescriptions containing cisplatin (chi-square test $p < 0.001$) or carboplatin (chi square test $P < 0.05$). Participants attributed errors to a culture where they were unable to ask questions, poor clinic organization, lack of knowledge and lack of essential equipment and resources.

The third aim study was to identify the nature and frequency of errors associated with administration of chemotherapy to patients and to explore their potential causes. The study was composed of mixed methods, using observation and critical incident interviews. More than 300 intravenous doses were observed, none of which were correctly prepared and administered to patients. None of the nurses wore appropriate protective clothing or adhered to aseptic technique. More than one third of intravenous doses were calculated inaccurately and more than one fifth of the doses were withdrawn inaccurately. Nurses attributed the errors to lack of training, supervision and resources. In conclusion, findings show that patient safety is of a low priority at the study hospital which is leading to a high risk of harm to both patients and HCWs. A set of four interventions were recommended as a result of findings from the current work and mapped to the COM-B model of the Behaviour Change Wheel. The intervention aim to change healthcare worker behaviour, through centralisation of chemotherapy preparation, standardisation of chemotherapy prescribing, implementation of incident reporting systems and standardisation of care. These interventions are also aimed at creating legislation and guidance to regulate the practice of healthcare workers dealing with cytotoxic chemotherapy.

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GLOSSARY OF TERMS

AE	Adverse Event
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AFRO	African Regional Office
AHRQ	Agency for Healthcare Research on Quality
ASHP	American Society of Health Systems Pharmacists
AUC	Area Under the Curve
BOPA	British Oncology Pharmacy Association
BSA	Body Surface Area
CDSS	Clinical Decision Support Systems
CI	Confidence Interval
CIT	Critical Incident Interview
COSHH	Control of Substances Hazardous to Health
CPOE	Computerised Physician Order Entry
CUSP	Comprehensive Unit Based Safety Programme
DoH	Department of Health (UK)
EML	Essential Medicines List
EMRO	Eastern Mediterranean Regional Office
EWR	Executive Walk Rounds
FMAQ	The Flight Management Attitudes Questionnaire
GFR	Glomerular Filtration Rate
HCW	Health Care Workers
HEPA	High Efficiency Particulate Air Filter
HMPS	Harvard Medical Practice Study
HSE	Health and Safety Executive
HSOPSC	Hospital Survey on Patient Safety Culture
IAA	International Atomic Agency
IARC	International Agency for Cancer Research
ICU	Intensive Care Unit

IOM	Institute of Medicine
ISOPP	International Society for Oncology Pharmacists
KBM	Knowledge Based Mistake
LFTs	Liver Function Tests
MaPSaF	Manchester Patient Safety Framework
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OR	Odds Ratio
PSC	Patient Safety Culture
PDI	Power Distance Index
PIL	Participant Information Leaflet
PPE	Protective Personal Equipment
PSCHO	Patient Safety Climate in Healthcare Organization Survey
PSCQ	Pharmacy Safety Climate Questionnaire
RCA	Root Cause Analysis
RFT	Renal Function Tests
RBM	Rule Based Mistake
RUM	Rational Use of Medicines
SAQ	Safety Attitudes Questionnaire
SCS	Safety Climate Questionnaire
SOP	Standard Operating Procedure
SUMASRI	Sudan Medical and Science Research Institute
UK	United Kingdom
US	United States of America
VA	Veterans Association
WHO	World Health Organization

CHAPTER ONE

1 GENERAL INTRODUCTION

1.1 Introduction

Evidence from developed nations suggests that a considerable number of patients are harmed by unsafe medical care and that between 44,000 and 100,000 patients die every year as a result of medical care in the United States of America (USA) (Kohn, 2000). These figures, published by the Institute of Medicine (IOM), are the result of extrapolating two studies conducted in the USA during the late 1980s and early 1990s; the Harvard Medical Practice Study (HMPS) (Brennan et al., 1991) and the Utah and Colorado study (Gawande et al., 1999). Before these were published, the harm to which patients were exposed was infrequently studied and prominent doctors were reluctant to draw the attention of the media and the public alike to medical harm (Vincent, 2010). Although, most of the evidence for patient harm is obtained from studies conducted in higher income countries, there is growing evidence of patient harm due to unsafe medical care in countries with low to middle incomes (Jha et al., 2010). The documented risks associated with medical care have placed it among other high risk industries such as aviation, a service that has achieved very good safety records. Ignoring harm associated with medical care is no longer an option for healthcare institutions and authorities who need to take forward steps in prioritizing patient care or otherwise be considered negligent (Vincent, 1989).

1.2 The Patient Safety Movement

In response to the IOM report, healthcare organizations, around the world, initiated research to identify the scale and type of harm to which patients were exposed. The findings from these retrospective record review studies revealed that 2.9 to 18% of hospitalized patients were harmed by unsafe medical care (Table 1-1). The studies can be considered comparable because of similar methodologies, however, the use of different definitions, criteria and the potentially different levels of healthcare quality may have led to the wide variation in the incidence of harm. Most of the work was large-scale, studying adverse events in up to 51 hospitals and involved obtaining records from a substantial number of hospitals (de Vries et al., 2008).

Table 1-1 The frequency of adverse events from landmark studies

Author	Country	No of hospitals	No of patients	Rate of AEs (% if not stated otherwise)	Rate of permanent disability (%)	Rate of death (%)	Preventability (%)
Leape 1995	USA	51	30,195	3.7	8.1	6.9	not reported
Wilson et al 1995	Australia	28	14000	16.6	13.6	4.9	51.2
Gawande et al 1999	USA	28	15000	3	9.4	5.6	54
Vincent et al 2000	UK	2	1014	11.7	6	8%	48
Davis et al 2002	New Zealand	13	6579	12.9	10.2	4.5	40
Baker et al 2004	Canada	20	3745	7.5	15.9	5.2	36.9
Michel et al 2007	France	71	8754	6.6 per 1000 days	1.5	0.6	35
Zegers 2009 et al	The Netherlands	21	7029	10.7	5	7.8	39.6
Aranez-Andres 2008	Spain	24	5908	9.3	N/R	4.4	42.60
Soop et al 2009	Sweden	28	1967	12.3	10.8	4.1	70
Wilson et al 2012	Egypt, Jordan, Kenya, Morocco, South Africa, Sudan, Tunisia, Yemen	26	15548	8.2	14	30	83

The landmark Harvard Medical Practice Study (HMPS) was originally intended for litigation purposes and identified the extent of patient harm caused by both negligent and non-negligent medical interventions (Hiatt et al., 1989).

The researchers investigated the type and incidence of adverse events in a group of acute non-psychiatric hospitals in New York, USA in 1984.

In this study, an Adverse Event (AE) was defined as:

"an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both" (Brennan et al., 1991) p 370

The HMPS involved the review of 30,121 patient records revealing that 3.7% of patients suffered a medical adverse event (AE) (Brennan et al., 1991). However, the vast majority of those did not result in serious disability, with 70% achieving complete recovery in less than six months. However, 0.4% suffered permanent disability and 1.7% died. A sub analysis of the medical causes of these AEs revealed that nearly half occurred due to a number of complications during the intra-operative or post-operative period , but that medicines as a single common causation were responsible for almost a fifth of those events (Leape et al., 1991). Among the medicines that led to AEs, antibiotics were the most common (16.2%) and anti-tumour agents (15.5%) the second most common (Leape et al., 1995).

Findings from this study prompted the lead researcher to publish the seminal paper "Error in Medicine" (Leape, 1994) which eventually led to the formation of the Committee of Quality of Healthcare in America by the Institute of Medicine.

In response to the high rate of surgery-associated AEs reported in the HMPS, Gawande and colleagues (1999), later undertook a similarly designed retrospective review of 15,000 medical records in hospitalized patients in Colorado and Utah. They reported that 3.2% of surgical patients suffered an AE, half of which were preventable (Gawande et al., 1999).

Subsequently, similar large-scale studies were conducted across the world. The method developed by the HMPS was adopted in all but one (Michel et al., 2007) of the major studies which were carried out in European countries (Vincent et al., 2001;Michel et al., 2007;Aranaz-Andres et al., 2008;Soop et al., 2009;Zegers et al., 2009;Jha et al., 2010), Australia (Wilson et al., 1995), New Zealand (Davis et al., 2002;Davis et al., 2003), Canada (Baker et al., 2004) and those commissioned by the WHO in developing and emerging countries (Aranaz-Andres et al., 2011;WHO, 2011a). The method entailed a two-step

process that consisted of an initial record screening by a trained researcher followed by separate screening by two trained doctors. The first step involved screening a sample of records and identifying those that contained at least one criterion associated with an AE from a predefined list. Examples of such criteria were admission into the intensive care unit (ICU), death and readmission into hospital (Hiatt et al., 1989). Records positively screened were then separately reviewed by two trained doctors in the second step, using a checklist for AE analysis. Record review is an established method in patient safety research and is important because it allows for screening when little is known about the situation, however, it has the potential for underestimating AEs and preventability (Michel, 2003).

The studies from Australia (Wilson et al., 1995), New Zealand (Davis et al., 2002), England (Vincent et al., 2001), Canada (Baker et al., 2004) and European countries (Aranaz-Andres et al., 2008;Michel et al., 2007;Schioler et al., 2001;Soop et al., 2009;Zegers et al., 2009), confirmed these findings and reported higher rates of AEs.

The Australian study reported a fivefold higher rate of AEs (16.6%) when compared to that reported in the US literature. The study reviewed a sample of 14000 medical records from 28 hospitals across two states in Australia using similar methodologies to those previously described by Leape and colleagues (1991). Half of the AEs were associated with surgery; 4.9% resulted in death, 13.7% resulted in permanent disability and half were judged to be preventable. There are several explanations for the differences in findings between the Australian and American studies. Most importantly, the Australian study was inclined in favour of identifying AEs because the objective of the study was to improve quality of care rather than identifying negligent cases for insurance and litigation claims (Thomas et al., 2000). This was seen with a much earlier American study intending to identify untoward outcomes in hospitalized patients which reported a similarly higher incidence (20%) of AEs (Schimmel, 1964). Differences in the level of detail contained in the Australian medical records, quality of Australian healthcare, the use of specialists in the study and differences in diseases between the two countries could further explain these differences. However all studies outside the USA reported higher frequency of AEs, mostly because the researchers used less restrictive definitions for an adverse event (Jha et al., 2010).

Research in the UK, also, confirmed findings from US studies. Vincent and colleagues reviewed 1014 medical records from two London NHS hospitals. Although this figure was not representative of patients admitted to London hospitals or even hospital patients around the UK, this study served as a foundation for further work. The study revealed that

a little more than 10% of admissions were associated with AEs. Although more than half of the patients recovered completely, but 34% sustained moderate disability, 6% had permanent disability and 8% died (Vincent et al., 2001). Similar to work conducted outside the US, this study reported a higher number of incidents than the US studies but this could be due to different interpretations of the criteria for identifying records with AEs. Furthermore, more records (26%) were chosen at the first stage in the UK in comparison to 16.6% in the US studies.

In response to these studies, governments and healthcare organizations published guidance on patient safety. The publication of the landmark report "To Err is Human"(Kohn, 2000) was a direct consequence of these studies. The report recognized that although individuals in healthcare systems need to be vigilant and aware, blaming individuals involved in errors was not the solution. The majority of errors were due to human factors but were both inevitable and preventable. In recognition of this, the report recommends that systems should be designed in order to standardize processes, reduce violations and deviations and offer safer healthcare. An important element in designing those processes was identification of service gaps that allow errors to take place. Hence, the key recommendation from this report was the creation of a national anonymous voluntary error reporting system, to allow identification of error-prone systems and thus focus on interventions to strengthen them.

The UK government, in turn, published the report "An organization with a memory" which focused on learning from errors(Department of Health, 2000b). Plans to implement the recommendations made in this report were set out in the landmark report, *Building a Safer NHS*. Similar to the US and central to the plan was the establishment of a mandatory reporting scheme for all mistakes that occurred within healthcare workplaces, with the aim of collating, analysing and assessing this information to identify areas of poor practice and to seek ways of avoiding common errors. Furthermore, the report aimed to establish a blame-free culture where lessons are learnt from errors to promote patient safety (Department of Health, 2000a). The National Patient Safety Agency (NPSA) was established for this purpose; to "*lead and contribute*" to improving patient safety within health services. The NPSA offered incident reporting services through the National Reporting and Learning service (NRLS), a system that collects and analyses patient safety incident reports supplied from staff in the NHS. Collected information is subsequently used to provide feedback and guidance to healthcare organizations to improve patient safety.

Worldwide, the fifty-fifth World Health Assembly adopted a resolution that urged member state countries to place an emphasis on strengthening safety in health care delivery and develop systems to monitor patient safety incidents (WHO, 2002b).

1.2.1 The World Alliance for Patient Safety

The World Patient Safety Alliance was launched in 2004 as a body of expertise to provide support to member states with the aim of improving the quality of medical care and reducing the incidence and severity of iatrogenic injury (WHO, 2005a).The alliance chose six areas of priority for action (WHO, 2005a) outlined in Table 1-2.

One of the first issues identified was the lack of AEs data from transitional and developing countries (Donaldson, 2005). With the exception of a limited number of small-scale studies, there was no published national work on the incidence of AEs in medical care (Carpenter et al., 2010). Furthermore, studies were limited in scope and tended to examine specific areas of medical practice (Carpenter et al., 2010). A review of studies in transitional and developing countries identified 23 studies on AEs, mostly conducted in a single hospital, with the exception of two that were large scale (Carpenter et al., 2010).For example, in Mexico a retrospective review of 836 records in a respiratory diseases hospital showed a 9.1% incidence of adverse events, 74% of which were preventable (Herrera-Kiengelher et al., 2005) and in Iran, a review of 70 postmortem reports of trauma patients showed that 26% of all trauma deaths was preventable (Zafarghandi et al., 2003).

Consequently, the WHO conducted a series of six awareness workshops across its regional offices; Asian region (WHO, 2007b), American region(WHO, 2007c), African region (WHO, 2007d) and Eastern Mediterranean Region (EMRO) (WHO, 2007e).

The workshops aimed to raise awareness about patient safety, prioritise areas of concern and provide training and a framework for health institutions in these regions to conduct patient safety studies in healthcare institutions. Subsequently a study (The Eastern Mediterranean and Africa Study- The EMAS) was carried out in the WHO African Regional Office (AFRO) and the Eastern Mediterranean Regional Office (EMRO) in 2007-2008 and published in 2011 (WHO, 2011a).

Table 1-2 World Patient Safety Alliance Priority Areas

Priority area	Action
The Global Patient Safety Challenge	Formulation of a two to three-year patient safety challenge which has been identified by an expert panel to pose a significant healthcare problem relevant to all member states. The first challenge chosen was "clean care", promoting infection control systems across the globe and the second is "safe surgery".
Patients for patient safety	This initiative was planned to empower patients to take leadership and advocacy roles to report and highlight patient safety incidents.
Taxonomy for patient safety	The WHO has developed an internationally accepted nomenclature and definition for adverse events. This serves to enable countries and researchers to report errors and near misses in a standardized manner.
Research for Patient Safety	Recognizing the role of research in providing the impetus of the patient safety movement, the WHO co-ordinates patient safety research in countries with developing and transitional economies. In addition, the alliance produces a methodological tool kit to enable other countries to conduct patient safety research.
Patient Safety Solutions	The WHO produced a booklet which contains a set of nine evidence-based solutions that have been shown to improve patient safety.
Reporting and Learning Systems	The WHO has launched an International Reporting and Learning Systems Community of Practice which is a body of experts from around the world who are charged with sharing learning, solutions, innovations and best practice.

The work used the two step retrospective review of medical records developed by the HMPS on 18,146 patients hospitalized in 2005, drawn from 26 hospitals from 7 countries, including Sudan (WHO, 2011a). The study revealed that 8% of hospital patients were harmed by adverse events, a finding similar to hospitals in the UK (Vincent et al., 2001), Australia (Wilson et al., 1995) and some European countries (Soop et al., 2009;Aranaz-Andres et al.,

2008). Most importantly half of AEs were preventable (50%) but caused considerable permanent disability (14%) and one third of patients died as a consequence(Wilson et al., 2012).This, however, is possibly an underestimation because the study design stated that if one patient had multiple AEs, only the most serious would be reported. The authors also recognized that there were limitations due to incomplete medical records which prevented proper detection of AEs. Inadequate record keeping in transitional and developing countries is a well-known and widespread issue (WHO, 2010). Nevertheless, the findings indicated that patient harm was evident and had more devastating effects than the reported data from developed nations.

Results from this study identified that therapeutic error was the leading cause of adverse events among hospitalized patients (Wilson et al., 2012). The contributory causes were not lack of resources, as previously revealed in maternal mortality studies conducted in the region (Sundari, 1992) but inadequate supervision followed by failure in implementation of treatment protocols.

With the exception of a small cross-sectional study conducted in Jordan (Hayajneh et al., 2010) to identify AEs associated with healthcare, most other studies emerging from developing and transitional countries have focused on medication errors. The Jordanian study used questionnaires with a combination of open-ended and close-ended questions to assess the frequency of errors and their contributory factors. Nurses reported that adverse events occurred in 28% of all inpatient admissions, with medication errors, wrong diagnosis, infections, bed sores and falls being the most commonly encountered. The study showed that more than half the adverse events were associated with drugs, which was similar to previous studies conducted in developed countries (Leape et al., 1991).

1.3 Adverse Drug Events

Adverse Drug Events (ADEs) are:

> "injuries *due to a medication" (Morimoto 2004 p307)*

Medications were the second leading cause of hospital-related AEs in a number of studies (Baker et al., 2004;Leape et al., 1991;Michel et al., 2007;Soop et al., 2009;Wilson et al., 1995;Zegers et al., 2009) and the leading cause of AEs in Spain (Aranaz-Andres et al., 2008). The HMPS identified that drugs were the single most common cause of AEs, amounting to almost 20% of the total (Leape et al., 1991).

ADEs are common, affecting up to 6.5 in 100 hospital admissions (Bates et al., 1995b) and have the potential to prolong hospital stay by up to 4 days (Bates et al., 1997). More importantly ADEs have the potential to increase hospital cost and patient mortality, resulting in a 100% increase in expenditure and three times as much in the risk of mortality when compared with controls (Classen et al., 1997).

In hospitals, patients in medical wards (Bates et al., 1995a) and patients in ICUs (Cullen et al., 1997) have been shown to have a higher incidence of ADEs than in other wards. Furthermore, older patients and those who stay longer in hospitals were at an increased risk of more severe ADEs (Bates et al., 1999a). ADEs were found to occur mostly at the prescribing stage (Morimoto et al., 2004;Runciman et al., 2003;Kaushal et al., 2001). Medicines associated with ADEs were commonly antibiotics, cytotoxics, cardiovascular agents (Leape et al., 1991), anticoagulants (Bates et al., 1993), analgesics (Classen et al., 1997), anti-epileptics (Gurwitz et al., 2005) and anti-diabetic drugs (Mills et al., 2008).

A study of US death certificates during 1983-1993 indicated that medication-related deaths increased during that period by 2.57 times and the rise in deaths was higher among outpatients compared with inpatients (Phillips et al., 1998). The authors found that this was not related to an increase in the use of prescription drugs, rather the change in healthcare strategy where patients were cared for in the outpatient setting. Other risk factors for medication-related death were gender and race, with males and those of black origin at highest risk. In contrast, findings from inpatient studies had negative associations with gender and race. A survey on patients presenting to four primary care centres in the USA showed that 25% of patients reported an ADE, much higher than inpatients (Gandhi et al., 2005a). The drugs more commonly implicated in outpatient-related ADEs were antidepressants and anti-hypertensives in comparison with antibiotics and cardiac drugs in inpatients (Bates et al., 1993).

Preventability and seriousness of ADEs has been confirmed in published research. Studies have shown that up to half of ADEs among inpatients (Gurwitz et al., 2005) and up to 90% among ambulatory care patients (Taché et al., 2011) are preventable. Previous research has shown that preventable ADEs can be serious, leading to life-threatening consequences in almost a fifth of affected patients (Bates et al., 1993). The majority of serious, life threatening and fatal ADEs are preventable (Gurwitz et al., 2005). Unpreventable ADEs are always caused by an Adverse Drug Reaction (ADR) but preventable ADEs may be caused by an ADR or a medication error (Bates et al., 1995a). ADRs are a subset of ADEs and according

to the WHO, they are untoward events suffered by patients when drugs are prescribed and administered using standard doses and methods (WHO, 2005b). ADRs are not rare, not always preventable and can have serious consequences. Therefore medicines were between the fourth and sixth leading cause of death in the USA (Lazarou et al., 1998). Similarly, wrong medication was identified as one of the leading causes of anesthetic AEs in early studies (Cooper et al., 1984). More specifically, dosing errors have been identified as the leading cause of ADEs among children (Kaushal et al., 2001).

The potential for ADEs is great considering the many stages which encompass the medication process, and conversely the potential for intercepting medication errors at each stage presents an important opportunity for preventing ADEs.

A prospective study detected ADEs in two large hospitals in the US (over 1500 beds in total), using self-reports by nurses and pharmacists as well as daily medication chart reviews. Extrapolated results from the findings indicated that about 6 ADEs occur per 100 non-obstetric hospital admission. Of the ADEs, 1% were fatal, 12% life-threatening, 30% serious and 57% significant. The rate of ADEs was highest among ICU patients, and more importantly, among the serious and life-threatening ADEs, 42% were preventable. Among the preventable ADEs, the most (56%) occurred at the prescribing stage, 34% occurred during medicine administration, 6% and 4% were identified at the transcription and dispensing stages, respectively. The authors estimated that 1900 ADEs can occur in a hospital per year, with varying severity (Bates et al., 1995b)

Errors occurring at the prescribing stage were often more preventable and because they occurred earlier in the medication process, they were more likely to be intercepted.

Prescribing errors can be both errors of omission and errors of commission. In a review of ADEs reported in Australia, the leading cause of hospital admission was failure to prescribe anticoagulants leading to deep vein thrombosis (Runciman et al., 2003). On the other hand, a systems analysis of the medication errors identified in the ADE prevention study was conducted by Leape and colleagues (Leape et al., 1995), identified that overdose was the most common type of medication error. Similarly, Classen and colleagues found that overdoses were often related to deterioration in renal or hepatic function (Classen et al., 1997). Other medication errors reported included; wrong dose, wrong choice, wrong drug, drug allergy, missed dose, wrong time and inadequate monitoring. The authors identified that there were four main causes for the above errors: lack of knowledge of the drug, lack of information about the patient, rule violations and slips. Since most of these errors

occurred at the prescribing stage, a rational step was to develop interventions that assisted doctors in prescribing decisions.

Leape and colleagues (1995) identified that system failures caused many medication errors and hence isolated interventions such as training and education were ineffective (Mills et al., 2008). Interventions showing some benefit in reducing the incidence of medication errors include: the involvement of pharmacists at the prescribing stage, intravenous systems, protocols and guidelines, Computerised Physician Order Entry (CPOE) and support systems for clinical decision making (Manias et al., 2012).

1.4 Medication errors in the EMRO region

Published data on medication error research in the EMRO region, is limited. For example, a review of medication error studies identified only 45 published articles from 15 countries (Alsulami, 2013). The authors listed 13 criteria for assessing the quality of published work and none of the articles included in the review met all criteria. One quarter of the studies failed to specify the type of medication error under focus and more than one quarter did not specify whether or not ethical approval had been obtained. Almost half the studies focused on prescribing errors, whilst others studied administration errors or focused on errors in paediatrics. The studies were heterogeneous in their study design and how they presented rates of error. Hence, the authors reported that they experienced difficulties in comparing medication error rate. Nevertheless, medication error rates associated with prescribing varied from 7.1% to 90% and those associated with administration of medicine varied between 9.4% and 80%. Similar to research conducted in western studies (Leape et al., 1995), the most common errors were dose errors, wrong frequency, wrong strength of drug and wrong duration of therapy. Most of the errors were related to antihistamines, antibiotics and anti-coagulant drugs. Similar to previous studies in western countries (Classen et al., 1997) researchers in the EMRO region reported that poor knowledge was a major contributor to medication errors and a small number of studies reported clinical severity of errors with one study attributing 26 deaths among nearly 3000 patients to medication errors.

Although the findings from this review indicate that medication errors in the EMRO region are widespread, comparison with western research is difficult, for two reasons. None of the identified studies used previously validated study designs and medication errors were poorly defined.

1.5 Safety using cytotoxic chemotherapy

Cytotoxic chemotherapy for cancer management was discovered during the second world war when nitrogen mustard used by bomber planes led to remission of lymphoma among affected pilots. These observations inspired the development of alkylating agents and later other drugs currently in use to treat cance. However, these medicines are non-specific and target both healthy and cancerous cells, leading to numerous side effects (Chabner, 2011). They have the potential to cause substantial long term and short term complications that may lead to poor quality of life, disability and death. Short term complications are easier to monitor and manage because they occur within a few days of the start of the chemotherapy. However, long term complications may occur anytime from the completion of the course of cytotoxic chemotherapy to decades after completion.

Short term side effects usually resolve within a few months from occurrence but can be severe enough to require hospitalization (Nurgalieva et al., 2009). Bone marrow suppression, notably neutropenia, can be life-threatening when patients become immunocompromised and contract infections (Crawford et al., 2004). Thrombocytopenia and anaemia requiring therapeutic intervention and dose modification are also seen (Nurgalieva et al., 2011).

Perhaps the most devastating of all complications for patients are nausea and vomiting (Hesketh, 1999) which can lead to dehydration and leave a strong psychological impact resulting in anticipatory emesis (Hesketh, 2008). Cytotoxic chemotherapy can lead to organ damage; renal failure (de Jonge et al., 2006), neuropathies (Windebank et al., 2008), mucositis and diarrhoea (Sharma et al., 2005) among other complications. The majority of chemotherapy-related complications are manageable, for example the administration of granulocyte colony stimulating factors to reduce the risk of neutropenia (Crawford et al., 2004) and the use of anti-emetics to reduce the severity of nausea and vomiting (Hesketh, 2008).Complications from cytotoxic chemotherapy often require dose limitation to mitigate the effects (Krischer et al., 1997) because it has been shown that lower doses are associated with a lower incidence of side effects (Partridge et al., 2001).

In contrast long term complications are not as easy to control and these include cognitive impairment (Tannock et al., 2004) cardiotoxicity (Krischer et al., 1997) and infertility in both males (Dohle, 2010) and females (Barton et al., 2013).

Most notably, cytotoxic chemotherapy causes an increased risk of carcinogenicity and teratogenicity via their mutagenic activity on mammalian chromosomes (Sieber et al., 1976), posing risks to patients and healthcare staff who are exposed to them. Consequently, the International Agency for Research in Cancer (IARC) has classified 24 cytotoxics as carcinogens or possible carcinogens, with all of them classified as teratogenic (Briggs et al., 2011). Decades ago, evidence emerged showing that the urine of nurses exposed to cyclophosphamide has mutagenic activity (Falck et al., 1979).

Cytotoxics can enter the systems of nurses and pharmacy personnel through accidental ingestion, aerosol inhalation (Hirst et al., 1984) and through dermal exposure (Fransman et al., 2004;Bos et al., 1997) via skin contact with contaminated surfaces. Isolated reports of primary cancers have occurred in Health Care Workers (HCWs) exposed to cytotoxics. Bladder cancer has been reported in a 39 year old pharmacist who had no other risks except the exposure to cytotoxics for a period of 20 years (Levin et al., 1993). Bladder cancer is a disease of older men but has been associated with occupational exposure to carcinogens such as cigarette smoking, rubber, chemicals and textiles (Wynder et al., 1977).

Most of this evidence came from an era when health and safety legislation was not in place and nurses would prepare cytotoxics on the bench in clinical areas without appropriate personal protection.

The body of evidence on occupational risks associated with handling cytotoxics poses challenges to both HCWs and their managers. It became obvious that HCWs should be protected from these risks. In the 1980s the US, UK and European bodies developed guidelines for the handling of hazardous chemical which requires workplace risk assessments to be conducted to identify substances that are hazardous to health and hence provide protection to employees. Guidelines were developed in the US, UK, Ireland, Denmark, Germany, Finland, Sweden and Australia (Carrington et al., 2010b;Jacobson et al., 2009;Allwood et al., 2002).

Subsequently, specific guidelines for the handling of cytotoxics were developed (ISOPP, 2007a;ASHP, 2002), in order to provide protection for HCWs. Guidelines stated that HCWs should be offered training in handling cytotoxics and use Personal Protective Equipment (PPE). Furthermore, they recommended that specific guidelines for preparation and written standard operating procedures (SOPs) should be developed and implemented. Further guidelines on prescribing, dispensing, administration and waste disposal were recommended (ASHP, 2002;Carrington et al., 2010b). In addition, detailed guidance on

prescription verification have also been recommended (Williamson, 2010;Kalyn et al., 2011).

Currently, chemotherapy prescribing is guided by strict protocols (ASHP, 2002) and verified by a pharmacist, nurse or another doctor (Cohen et al., 1996), before administration to patients. HCWs involved in the cytotoxic chemotherapy process ideally should be certified or appropriately trained in order to handle these drugs (Fischer et al., 1996). All doses for cytotoxic chemotherapy should be prepared in a centralised pharmacy (Allwood et al., 2002), where risks of preparation error (Anderson et al., 1983) and occupational exposure are reduced (Mason et al., 2005). The inherent toxicity of these agents leaves a very small margin for error and medication errors have the potential to cause disastrous consequences for the patients' lives as well as incurring significant costs in negligence claims and additional healthcare, required to mitigate the outcomes.

1.5.1 Adverse Drug Events associated with cytotoxic chemotherapy

Although less commonly prescribed than other medicines, cytotoxic chemotherapy agents are the second most common drugs associated with AEs (Leape et al., 1991), can cause death (Fyhr et al., 2012) and are among the top ten medicines involved with preventable ADEs (Kanjanarat et al., 2003), causing up to 11.2% of ADEs (Mills et al., 2008).

Until the early 1990s, the only information regarding medication errors and adverse events associated with cytotoxic chemotherapy were from case reports and national voluntary reporting systems. In the USA, Wiengart investigated adverse events associated with the use of oral cytotoxic chemotherapy during a five year period (Weingart et al., 2010). The authors collected information from two US national error databases, incident reports from 16 academic cancer centres and a literature search. They identified 508 incidents, of which one fifth were associated with adverse events. Of the incidents associated with adverse events, most resulted in minimal harm but 12 resulted in death, 1 resulted in permanent disability and 26 patients required hospitalization.

One highly publicized case occurred in a prominent cancer centre in the US and one of the victims was a health journalist for the Boston Globe who died suddenly after receiving high dose chemotherapy for breast cancer (Altman, 1995). Investigations two months later revealed that the patients received four times the intended doses of an cytotoxic drug as part of a phase I research trial (Grant, 1999). The news was highly publicized and made the headlines of 28 newspapers over 3 years (Conway et al., 2005).

This incident, along with others, especially those involving the inadvertent intrathecal administration of vincristine, led the WHO to propose changes in how cytotoxic chemotherapy should be processed. Vincristine, a vinca alkaloid, works by arresting the cells during mitosis by binding to the mitotic spindle (Chabner, 2011). Vincristine can be used in combination therapy to treat lymphomas, leukaemias and solid tumours (Schulmeister et al., 2004). One of the major limitations of vincristine is neuropathy and its vesicant effect which means it can only be given via the intravenous route (Sullivan et al., 1977). When administered intrathecally, vincristine causes severe and irreversible CNS damage, followed by ascending paralysis, coma and death (Gilbar et al., 2007). Between 1968 and 2007, 38 cases where reported, from different countries, where vincristine was given in error via the intrathecal route (Noble et al., 2010). Although rare, such incidents had devastating consequences with some patients experiencing permanent nerve damage (Qweider et al., 2007), however, most died (Reddy et al., 2011)

In the UK, because of similar errors, an external inquiry was held into the case of a patient who died because of inadvertent administration of vincristine in a cancer centre in Nottingham. The report concluded that the error occurred as a result of 40 system failures that encompassed organizational errors at the national and the institutional level. The report recommended changes to the National Acute Lymphoblastic Leukaemia guidelines by scheduling intrathecal medicines on different days to intravenous medicines. In addition, changes were recommended for labelling, transport, storage, ordering, administration, training, and the involvement of a third party, including patients and their relatives, for extra verification prior to any administration taking place (Toft, 2001). In response to these reports, the DoH and the NPSA issued guidance on the safe prescription, dispensing, transport and administration of vinca alkaloids, which among other, included the recommendation that they should be prepared in a mini-bag rather than a syringe (NPSA, 2008). This measure was introduced to serve as an alert to doctors administering intrathecal medicine which are always prepared in small volume syringes. A recent review of vincristine incidents in the UK revealed that this specific error has not been recorded since the issuance of this guidance(Franklin et al., 2014).

1.5.2 Incidence of medication errors and adverse events associated with cytotoxic chemotherapy

Few studies on chemotherapy-associated medication errors or adverse events have been published (Schwappach et al., 2009). Moreover, the findings from these studies are not comparable for several reasons. Studies often use different definitions of error (Table 1-3) or study design or different settings (Table 1-4). Furthermore, some studies focused on paediatrics whilst others studied adults or had limited scope and studied one aspect of the chemotherapy process. Consequently, a common finding amongst all studies was the limited generalisability of data, as it was usually collected from single hospitals or cancer centres, involving small sample sizes. For example, a study conducted by Pichon et al (2002), which aimed to identify transcription and omission errors in prescriptions among 22 oncology patients. A total of 89 out of 150 prescriptions were found to contain either a transcription error or omission error (Pichon et al., 2002).

Nevertheless, these studies show the evidence that medication errors associated with chemotherapy are common and occur mostly at the prescription stage (Ranchon et al., 2011). Ranchon and colleagues (2011) analysed reported errors occurring in more than 22,000 cytotoxic chemotherapy prescribed to cancer patients in a cancer hospital in France, over a period of one year. The study design involved mixed methods, prescription review, observation of pharmacy preparation errors and voluntary reporting of administration and follow up of errors. The authors reported that 5.2% of drugs were associated with an error, with 91% occurring at the prescription stage, 8% at the preparation stage and 1% at the administration stage. This is unlike other medication error research which involved record review and identified higher rates of administration errors (Bates et al., 1995b). Most of these errors resulted in potential ADEs because the vast majority of errors were intercepted, with only 13 reaching patients, mostly causing no harm. The authors calculated that if the intercepted errors had reached patients this would have resulted in an increase in hospital stay by 219 days, which would in turn increase expenditure by over 92,000 Euros in hospital stay and additional drugs.

Medication errors causing potential ADEs are a significant concern when dealing with chemotherapy as they can also happen among ambulatory patients (Gandhi et al., 2005a). Similar to previous medication error research (Bates et al., 1999a;Bates et al., 1995b) Gandhi and colleagues (2005) undertook a large study at a major cancer centre in the US involving record review, in addition to incident self-reports from nurses, pharmacists and

doctors. The authors reviewed more than 10,000 prescriptions of cytotoxic chemotherapy, in both paediatric and adult outpatients receiving both oral and intravenous medicines (Gandhi et al., 2005a). They found the medication error rate was 3% (306 in 1000 prescriptions) in both paediatrics and adults, of which 2.5% had the potential to cause ADEs. A higher rate of errors was reported from a larger study in Germany, that showed 17.1% hospital in-patients receiving cancer chemotherapy were affected (Markert, 2009). This high incidence can be explained because the authors included in their analysis medication errors, administrative errors, ADRs and all cause AEs, which were not necessarily related to the use of cytotoxic chemotherapy. Markert and colleagues (2009) undertook a mixed method approach, both prospective cohort study and analysis of incident report databases over three years. The study included a larger study sample (2,337 patients and 22,216 chemotherapy prescriptions) than Gandhi's et al (2005) work. The actual incidence of chemotherapy error was similar (3.8%) but they detected a larger number of errors in administrative details. A considerable number of those medication errors were intercepted, because only 0.079% of errors had reached patients, mostly causing no harm. Other errors were missing patient details (4.5%) and missing written consent forms (8.7%).

Un-intercepted medication errors associated with chemotherapy have the potential to cause serious consequences to patients. An analysis of medication errors associated with chemotherapy reported to a Swedish error reporting system revealed that prescribing errors cause most harm (Fyhr et al., 2012). Over a period of twelve years, 60 medication errors were reported to the Swedish error reporting system. Among these, prescribing errors (n=25) caused death among 6 patients and harm among 15 patients, whilst pharmacy preparation errors (n=25) caused harm among 5 patients and administration errors (n=10) caused harm among 4 patients.

Similar to findings from the Swedish error reporting system, a review of chemotherapy-associated medication errors reported to the United States Pharmacopeia Medication Error Reporting Program (USP-MER), reported a high incidence of AEs associated with prescribing. The analysis showed the most common cytotoxics associated with adverse events in patients were platinums (Mehta et al., 1998). In their report, Mehta and colleagues (1998) identified that among 40 errors reported to the USP-MER, 28 had reached the patient. The authors were able to find circumstances associated with the 28 incidents and identified that look-alike, sound-alike drugs was the most common cause of medication errors. In these cases, the wrong drug would be prescribed, transcribed or interpreted from the prescription, resulting in an overdose in most instances.

Table 1-3 Definitions of medication errors/adverse drug events in research conducted on medication errors involving chemotherapy

Reference	Definition of a medication error/adverse drug event
Escoms et al., 1996	Lack of data or error in the preparation stage, labelling stage or arrangement stage according to the procedure at the studied setting.
Flynn et al. 1997	A deviation of the actual compounding process from specification in the pharmacy's patient-specific intravenous label or the hospital policies and procedure for intravenous compounding
Limat et al., 2001	The error involves all aspects of the preparation according to local procedure at the setting under study.
Pichon et al., 2002	Incompleteness of a prescription or incompleteness of transcription. There is no specification of what comprises a complete prescription.
Womer et al., 2002	Errors in the ordering or administration of chemotherapy
Gandhi et al., 2005	A medication error is any error in the medication process. A potential adverse drug event is a medication error that has the potential to cause patient harm.
Slama et al., 2005	All avoidable errors that could lead to the inappropriate use of medication or cause harm to patients according to the guidelines of the American Health Systems Pharmacists.
Ford et al., 2006	A medication administration error (MAE) is a preventable mistake during drug administration due to errors in ordering, dispensing and administration. An adverse drug event is a significant patient injury or discomfort resulting from an MAE.
Robinson et al., 2006	Modification, clarification and omission of items on a cytotoxic chemotherapy prescription
Taylor el al., 2006	Administration error in the home, prescribing error by the doctor or dispensing error by the pharmacist
Voeffrey et al., 2006	Errors in the prescribing, dispensing, administering or monitoring of a drug.
Rinke et al., 2007	The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim
Serrano-Fabia et al.,2009	An error that occurred during prescribing, pharmaceutical validation, preparation, dispensing, administration, and follow up.
Markert et al., 2009	A medication error is an error in the chemotherapy, co-medication, patient data and missing consent forms. A severe adverse event was an event leading to unexpected fatality, referral to ICU, an extravasation, an unscheduled operation and other serious events not related to the side effects of the drugs.
Walsh et al., 2009	An error in drug ordering, dispensing, administering or monitoring
Weingart et al., 2010	The failure of a planned action to be completed as intended of the use of a wrong plan to achieve an aim

Table 1-4 Characteristics of research conducted on medication errors involving chemotherapy

Reference*	Setting	Population	Data collection period (months)	Data collection method	Sample size	Incidence rate (% unless stated)
Gandhi et al., 2005	OP	Adults/Paediatrics	9	Chart review	1606	3
Limat et al., 2001	CRU	Cytotoxic preparations	18	Observation	30,819	0.45
Markert et al., 2009	IP/OP	Adults	24	Observation	22,216	17.1
Pichon et al., 2002	IP	Paediatrics	NR	Chart review	20	11.9
Rinke et al., 2007	D	Paediatrics	60	Analysis of database	NA	0.01
Robinson et al., 2006	IP	Paediatrics	12	Chart review	~10,000	P- 0.73 A- 0.06
Schulmeister 1999	IP/OP/H	NR	NA	Questionnaire survey	1240	63
Serrano-Fabia et al., 2009	IP	Adults	24	Observation	1311	20.9 /1000 patient days
Slama et al., 2005	IP	Prescriptions	6	Observation	2862	27.6
Taylor el al., 2006	OP	Paediatrics	2	Chart review/survey	92	9.9
Voeffrey et al., 2006	IP	Prescriptions	15	NR	940	15
Walsh et al., 2009	OP	Paediatrics	9	Chart review	1,379	8.2
Weingart et al., 2007	IP	Adults	7	Survey	202	2.5
Weingart et al., 2010	IP/OP/H	Paediatrics	60	Analysis of error database	NA	NA
Womer et al., 2002	IP	Adults	NR	Observation	NR	6.2 per 1000

A: actual errors; CRU: Cytotoxic reconstitution unit, D: Database for reporting error, H: Home setting, IP: inpatient, OP: outpatient, NA: Not Applicable, NR: Not reported; P: potential errors

An example of these was when carboplatin was misinterpreted as cisplatin; the latter is more potent and is given at doses which are usually around one quarter of the carboplatin dose. Hence such errors potentially carry the risk of giving the patient a considerable overdose. Six cases were reported, with 5 deaths and one patient who sustained renal failure and irreversible hearing loss. The second most common cause of errors was giving the total required drug over one day rather than splitting the dose over a number of days. For example, a prescription of cyclophosphamide 4g/m^2 over four days misinterpreted and given as cyclophosphamide 4g/m^2 given daily on days 1-4.

1.5.3 Factors contributing to Adverse Drug Events occurrence in chemotherapy

In the reports submitted to US based adverse events databases, the two most common contributing factors to ADEs associated with cytotoxic chemotherapy were human factors and miscommunication (Weingart et al., 2010). In a survey conducted among oncology nurses in US hospitals, the respondents attributed these errors to lack of experience (76%), unclear prescription (66%), stress (57%) and fatigue (29%) (Schulmeister, 1999). Poor knowledge and lack of confidence were reported to be a considerable cause for concern when prescribing chemotherapy among junior doctors in a qualitative study in Nigeria (Ajemigbitse et al., 2013a).

Other factors contributing to errors when using cytotoxic chemotherapy, reported in the literature, include the use of verbal orders (Fischer et al., 1996) the use of a large variety of cancer regimens (Gandhi et al., 2005a), shared care (Gilbar, 2001), lack of information about the cytotoxic chemotherapy (25%) and unclear labelling (1%), the use of central intravenous catheters (Mehta et al., 1998) and look-alike, sound-alike drugs (Kovacic et al., 2011).

Among patients, a considerable risk factor was the requirement for dose reduction due to co-morbidities and toxicities associated with cytotoxic chemotherapy when used with organ impairment (Ranchon et al., 2012).

Although, to date, there is little known about the impact of medication errors associated with chemotherapy in developing countries, findings from western countries indicate that they may be common and are expected to have tangible implications for patients. Patients often have multiple co-morbidities such as tuberculosis where the use of medications can affect the pharmacokinetics of cytotoxic chemotherapy , patients are malnourished, have

different pharmacogenomics (Magrath, 2003), present with very advanced disease and compromised organ function (Hamad, 2006).

1.5.4 Preventability of medication errors associated with cytotoxic chemotherapy

Given the complexity of chemotherapy regimens, and in order to provide safe, evidence-based cost-effective therapies, the use of these agents should follow agreed protocols or international guidelines (Kalyn et al., 2011, WHO, 2002a). Tumour-specific protocols have been published by a number of national and international agencies, usually modified or adopted by specialist cancer centres, to guide prescribers in decision making and standardize treatment among patients (Goldspiel et al., 2000). Furthermore, guidelines on the prescribing process (NPSA, 2010b), validation of prescriptions (Williamson, 2010), preparation of cytotoxics (ISOPP, 2007a) and administration of these drugs (Jacobson et al., 2009) have been developed to ensure their safe use. Although most cancer centres now prescribe chemotherapy according to these guidelines and protocols, the impact of these measures has not been formally assessed. Other interventions to improve the use of cytotoxic chemotherapy have been introduced but the data on reduction of medication error is contentious.

Although medication errors associated with chemotherapy are frequent, the vast majority are intercepted before they reach the patient. The comparatively high incidence of prescribing errors associated with cytotoxic chemotherapy meant that many interventions targeted the prescription process. The involvement of a team of HCWs is important for prevention of errors. It is more likely that most prescribing errors will be intercepted because the prescription in most cases is seen by at least two more HCWs before it reaches the patient (Garzás-Martín de Almagro et al., 2008). Hence, these subsequent steps may be regarded as defenses against errors.

This was confirmed in a prospective cohort study conducted in Spain (Serrano-Fabia, 2009). A multi-disciplinary team identified errors associated with the cytotoxic chemotherapy medication process among 1311 patients, over a one year period (Serrano-Fabia, 2009). The authors identified 276 medication errors (20.9 per 1000 patient days), of which most occurred at the prescribing stage (75.7%). Pharmacists contributed substantially to prevention of errors because only 4.3% of prescribing errors reached the patient. Nurses administering the drugs acted as the final defence against errors and they were able to stop most pharmacy preparation errors, with only 14.5% reaching patients.

The importance of HCWs as a team to detect and intercept errors was confirmed in an earlier Spanish study that analysed errors reported to a hospital incident reporting database. During a three-year period, 268 medication errors were reported, most of which were detected by nurses and pharmacists (54.1% and 39.6% respectively). The remainder were detected by doctors and other HCWs, with one detected by patients.

In addition to input from HCWs, and to further improve the prescription process, many cancer centres have adopted standard prescription templates These forms contain all the chemotherapy protocol particulars that a prescriber needs to complete in order to prescribe chemotherapy, accurately (Gilmore et al., 1998;Dinning, 2005;Goldspiel et al., 2000). These have printed spaces for laboratory data obtained from the patient, patient details, names and standard doses of the chemotherapy agents required and supportive therapy. An example where these standardized templates have shown benefit can be described from data published in the US. A multidisciplinary team was involved in creating standardized prescription templates for cytotoxic chemotherapy in an oncology hospital in the US (Dinning, 2005). The authors reported that the uptake of the standardized prescription templates increased to 70% in the span of one year, which may infer their ease of use and acceptability. Although not formally assessed, the authors reported that omissions and ambiguities with prescriptions were decreased substantially after implementing the standardized templates (Dinning, 2005). Following a similar intervention in another US oncology centre, the use of prescription templates was reported to contribute to a 36% reduction in errors associated with omissions, look-alike, sound-alike drugs and ambiguities in the prescription (Dumasia et al., 2006). Further improvements to prescribing were achieved when Computerized Prescriber Order Entry (CPOE) was introduced. Early studies in general medicine have recognized the impact of CPOE on prescribing errors (Bates et al. 1999) and before/after interventional studies have shown that these systems reduce prescribing errors and pharmacy interventions (Donyai et al., 2008). CPOE are computerised systems that standardise prescribing and ensure legibility and completeness of prescriptions (Kaushal et al., 2003). They have varying degrees of inbuilt Clinical Decision Support Systems (CDSS), ranging from basic guidance regarding drug doses, routes and frequencies to more sophisticated systems which can perform drug interaction checks, drug allergy checks and can match individual patient characteristics to clinical guidelines, providing patient-specific recommendations (Bates et al., 2001).

A number of studies have shown the benefit of CPOE in reduction of chemotherapy-associated prescribing errors. For example, researchers in Spain implemented a CPOE which

involved entering the centre's specific protocols into the system. The prescriber would access the system, choose the treatment protocol and enter the patient's data (Huertas Fernandez et al., 2006). The system would suggest doses of drugs to be prescribed according to the patient's height and weight and the chosen protocol. Once the prescriber completes the prescription, it is automatically transmitted to pharmacy where pharmacy preparation worksheet, labels and nursing administration sheets are produced. Implementation of such a system resulted in substantial reductions in omission and ambiguity errors. However, certain dose errors which were caused by inappropriate decisions regarding dose reductions were reported with computerised prescriptions (Huertas Fernandez et al., 2006). To improve decisions with doses tailored to specific patients, CPOE with CDSS features that offer suggestions for these dose changes are necessary (Bates et al., 2001). An example of the effectiveness of such a system in oncology has shown that dose errors are rare (Voeffray et al., 2006). In a Swedish cancer hospital, Voeffray and colleagues (2006) implemented a CPOE with added CDSS that included generating suggested dose reductions in case of organ impairments and alarms for dose changes as well as unusual doses. They studied prescribing error rates for 15 months before CPOE implementation and 21 months after the intervention. Prescribing error rates fell from 15 % to less than 1% with no dose errors. Furthermore, uptake of recommended chemotherapy protocols increased by 50%.

Although CPOE with CDSS have shown improvement in medication safety, their implementation in cancer care is limited. A review of 100 interventional articles on the outcome of CDSS shows that systems which feature advanced features which aid decision-making, using guidelines and information technology, are now in use in many healthcare settings and have been applied to cancer prevention strategies, mainly in the primary care setting (Garg et al., 2005). Their implementation in cancer management in secondary and tertiary care is limited (Fox et al., 2009).

The use of CPOE and CDSS cannot remove error entirely. Prescribers have been shown to circumvent alarms in these systems, sometimes leading to errors (Nerich et al., 2010). The systems are costly and require intensive input from the hospital to ensure their success. Factors that improve implementation include HCW training as well continuous monitoring to ensure that protocols and guidelines are adhered to (Bates et al., 2003).

However, improvements to the prescribing process would be likely to have little impact on preparation errors and administration errors. Interventions targeting the whole system are expected to reduce the incidence of errors further (Leape et al., 1995). Further automation

of the chemotherapy process that focuses on product verification includes electronic check of product identity at the preparation stage and administration stage (Bonnabry et al., 2006).

Automation and use of information technology is expected to be implemented in a number of healthcare settings. However, improvements to chemotherapy processes can be achieved using more holistic measures. These require the inclusion of healthcare in improvement measures that may be based on education, improved communication, error reporting and the implementation of SOPs. Informed multidisciplinary teams that adhere to standard guidelines provide safer care. They report errors and learn from high risk situations and perform double checks in the medication process and intercept errors before they reach a patient (Goldspiel et al., 2000).

1.6 Approaches to error

Blaming a doctor, pharmacist or nurse for a medical error is very satisfying (Reason, 2000) as the investigation is completed quickly and the individual blamed suffers the consequences of their actions whether it be that they are stopped from working, reprimanded or punished (Palmieri, 2008). The persons approach is fundamentally wrong for patient safety because individuals working in institutions where blame is prominent would be afraid to report errors and hence will be unable to learn from them (Wu Aw, 1991).

Charles Perrow proposed the pessimistic view that in complex organizations accidents are prone to happen (Perrow, 1981); that it was in the nature of humans working in complex organizations to make errors. However, when looking at other industries, especially aviation, the level of safety is apparent. Aviation has reached this level by investigation of accidents using a systems approach (Reason, 2005).It can be argued the delivery of healthcare is as complex a system as aviation (Helmreich, 2000), if not more complex, and hence, the interactions between healthcare staff in the operating theatre may be similar to aeroplane cockpits (Sexton et al., 2000). Applying lessons learned from aviation and indeed other safe industries such as nuclear power plants, in healthcare systems can improve safety.

1.7 Human error theory

James Reason proposed that, in complex systems, such as those that exist in healthcare, harm to patients is prevented by defensive layers, some of which are engineered (such as computerized medication systems) while others rely on people (doctors, nurses and pharmacists) as well as procedures and administrative controls barriers (Reason, 2000). Their function is to protect patients from the risks associated, however each defensive layer has several weaknesses, akin to the *'holes'*, of a Swiss Cheese. These *'holes'* in the system are constantly changing and when they momentarily align they allow the trajectory of error to occur, bringing harm closer to patients (Figure 1-1). These holes arise due to two reasons, active failures and latent failures. Understanding the interplay between these two factors allows for a proactive approach to risk management, where interventions are targeted at building better defenses in the system (Reason, 2000).

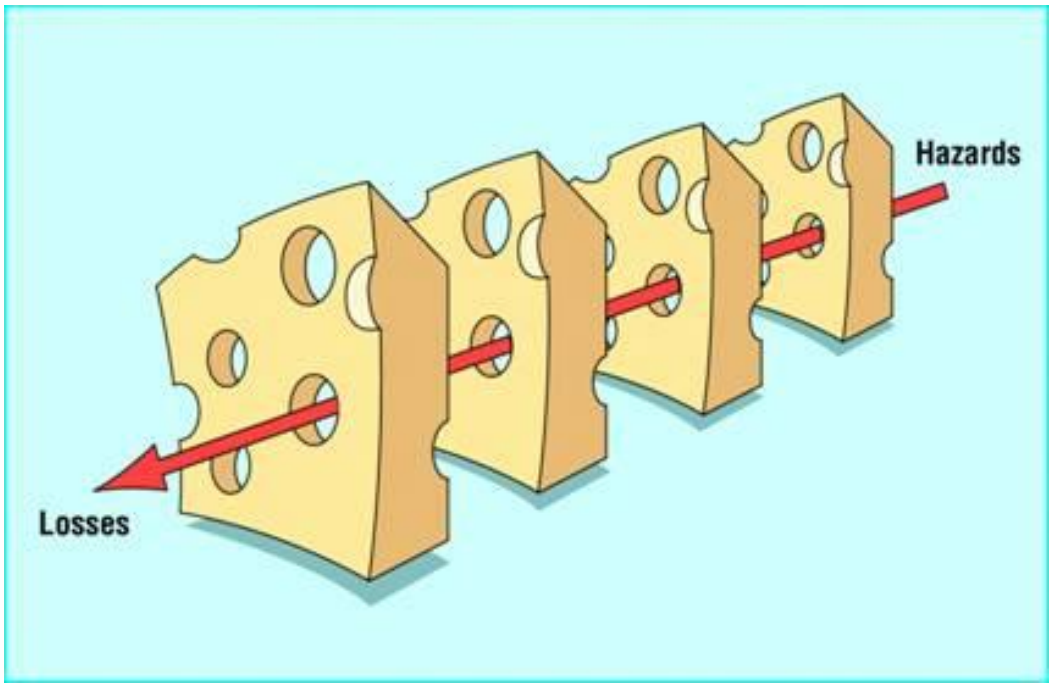


Figure 1-1 Swiss cheese model of how defences, barriers and safeguards may be penetrated by an accident trajectory (Reason 1990 p 393)

Active failures are unsafe acts which can be divided into two broad categories; errors and violations. Errors are seen as breakdowns in normal cognitive processes whereas violations occur due to deliberate deviations from safety procedures and rules (Reason, 1990).

Errors are related to a hierarchy of human cognitive performance developed by Rasmussen (1983) and can be defined as:

'*the failure of planned actions to achieve their desired ends- without the intervention of some unforeseeable event'* (*Reason, 1998 p 71*)

Failures at the level of execution are "*skill-based errors*" that occur during automatic the performance of routine tasks in familiar circumstances, and require little conscious attention. According to Reason (1990), these errors of *"omission"* are associated with failures in attention which may be caused by distractions, interruptions and memory failures and can be divided into two main types; slips and lapses (Figure 1-2).

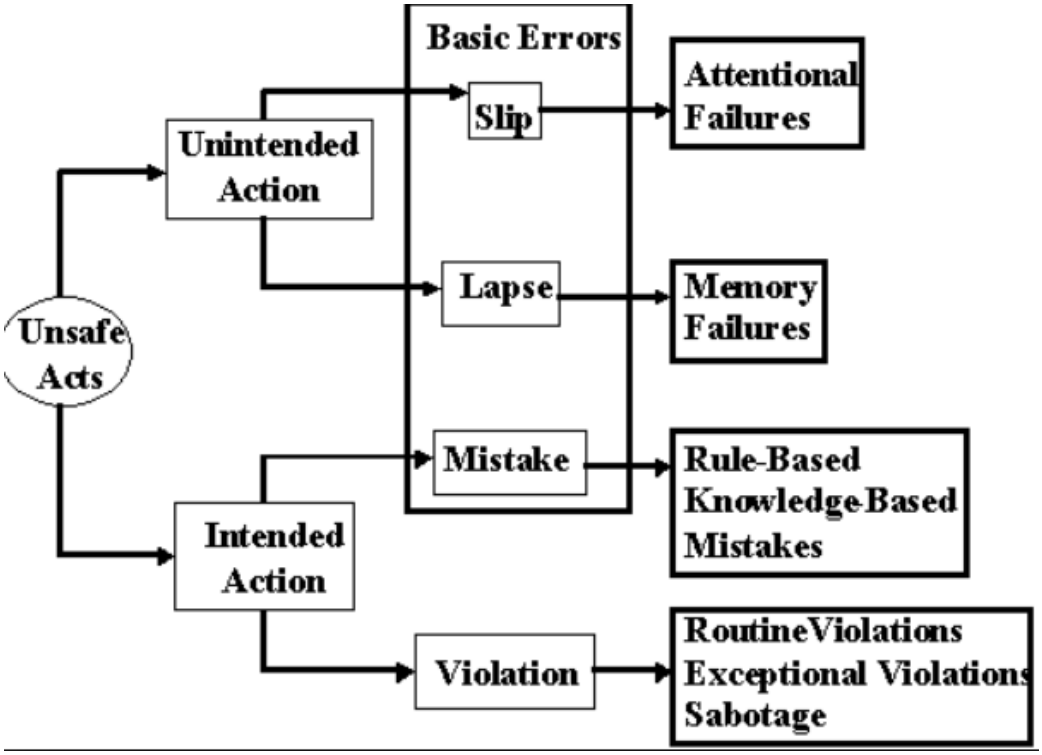


Figure 1-2 A summary of the psychology of unsafe acts (Reason 1990 p207)

A slip is an action that is carried out with the correct intention but the execution is faulty, whereas a lapse is a failure to execute an action due to distractions or memory failures. Mistakes on the other hand are decision-making failures which occur at higher levels of the human cognitive performance. They occur during performance of tasks that require problem solving, and although the execution is correct, the intent is incorrect. Reason (1990) divides these into two types; "Rule-based mistakes" (RBM) and "Knowledge-based mistakes" (KBM). RBMs occur during the execution of tasks which are governed by previously acquired training, experience or set rules and procedures. These errors may be

in various forms but are associated with misapplication of a "good rule" or application of a "bad rule". KBMs on the other hand, occur in novel circumstances where HCWs are required to depend on conscious reasoning to derive a course of action without the necessary background training, experience or task based rules (Reason, 1990).

In this context, violations are deliberate actions that intentionally deviate from practices and occur within a regulated social context. They fall into three main groups; routine violations, optimising violations and situational violations. In routine violation, the HCW would habitually cut corners, whereas in optimising violations the actions are to further personal rather than task related goals. HCWs who are involved in situational violations take the path available to getting the job done because the rules and procedures are seen as to be inappropriate (Reason, 1995).

Active failures are distinct from latent failures because the effects of the former are more immediate whereas the later tend to lie dormant in a system and can only become evident in the presence of an unsafe act. Active failures are unsafe acts committed by HCWs who have direct interaction with the patient, whereas latent failure stem from actions and decisions taken by management or decision makers who are not directly involved in the workplace (Vincent et al., 1998).This distinction is necessary when causality analysis are conducted after an adverse event has taken place (Figure 1.3).

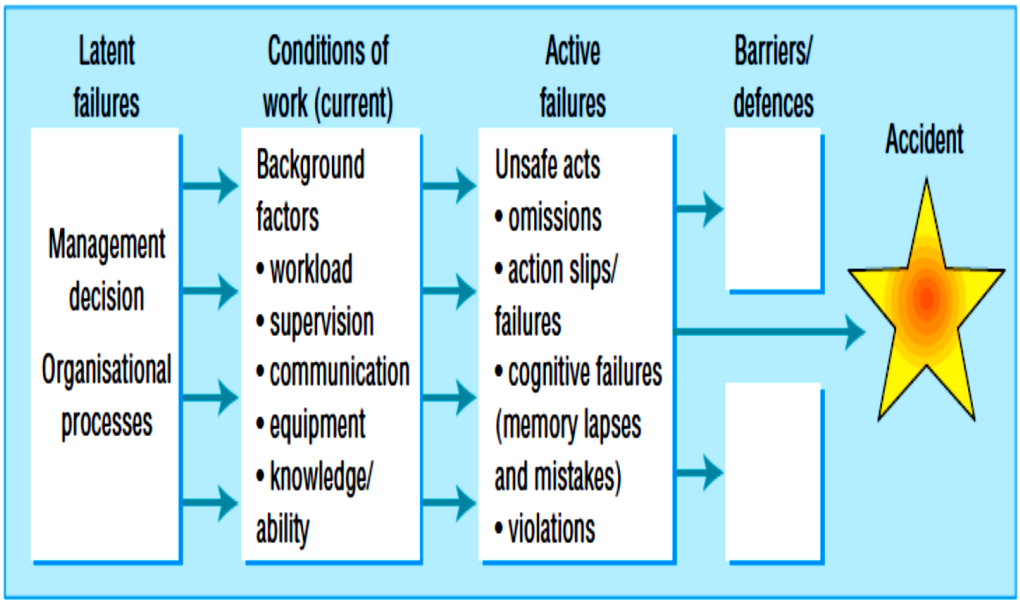


Figure 1-3 Framework for analysing risk and safety in clinical medicine (Vincent 1998 p1155)

The sequence of the accident (adverse event) begins with the fallible decisions made at the managerial and organizational level. These are decisions which are concerned with issues such as planning, scheduling, policy making, communication and maintenance. These latent failures are transmitted along organizational and departmental pathways to areas of patient care where they create conditions that provoke errors and violations. This description forms the basis for a framework to analyse risks and safety in clinical medicine (Vincent et al., 1998). The framework enables researcher to analyse clinical incidents in a manner that considers all possible influences rather than focusing on HCWs at the sharp end. The Reason's framework has been used in a number of previous medication error research (Dean et al., 2002a;Taxis et al., 2003a;Tully et al., 2009) and provides the philosophical underpinnings in the current study.

1.8 Overview of the study setting

This study explores patient safety in cancer care in a Sudanese cancer centre, an African country, south of Egypt, east of Chad, lying on the western coast of the Red Sea (Figure 1-4). The country has recently split, leading to formation of the world's newest country, South Sudan. This thesis is concerned with research conducted in the northern section of Sudan, now known as The Republic of the Sudan.

There are no confirmed data for the size of population in this country, since the split from the south, but there are estimates ranging from 30 million to 49 million (WHO, 2013a). The country comprises 15 states, with nearly one sixth of the population living in the national capital, Khartoum (Central Bureau of Statistics- Republic of Sudan, 2008). Although the Sudanese people are from different ethnic groups, each with their own local dialects, most are Arabic-speaking Muslims.

Organized heath care started in the late 1800s when it was delivered by the British colonial army but the first Ministry of Health was not established until 1949 (WHO, 2009). Currently, the health system comprises three levels (FMoH, 2007); the federal level, state level and locality level.

The Federal Ministry of Health (FMOH) is the ultimate authority in Sudanese health care, concerned with policy making, strategic planning and international co-ordination, while the state level is responsible for policy making and implementation and the locality level is concerned with service delivery (FMoH, 2007). The state level is responsible for running

secondary care hospitals, teaching hospitals and tertiary care specialist hospitals which lie within each state.

Healthcare delivery in Sudan is influenced by issues commonly affecting developing countries in the region (Parkin et al., 2008). National poverty, a long history of internal conflict and inadequate resource allocation results in health services that are underfunded, inadequately equipped (WHO, 2003) with inequitable distribution (Joseph, 2007). Healthcare in Sudan is heavily burdened with infectious diseases, malnutrition, maternal and child mortality, and a fragmented primary health service (FMoH, 2007a).

The recent conflicts in Darfur, coupled with the previous long conflicts in the south, have displaced people into the outskirts of the major cities. This has created *ad hoc* dwellings around the major cities, principally Khartoum the capital, (Ibrahim et al., 2014) where there is disproportionate input from planning authorities and consequently, a greater number of people are overcrowding the existing health facilities (Klaassen, 2007).

Although a great deal of attention is directed towards eradication of infectious disease, cancer is fast becoming a significant cause of death in African countries like Sudan (Parkin et al., 2008). Cancer was reported to be the third cause of recorded hospital mortality , amounting to 5% of all deaths (Hamad, 2006). This figure may seem small but the actual cancer incidence cannot be extrapolated from death certificates because they are usually deficient in major details (El Nour, 2007). Indeed, more than 95% of deaths occurring outside hospitals are not recorded (Abdalla et al., 2007).

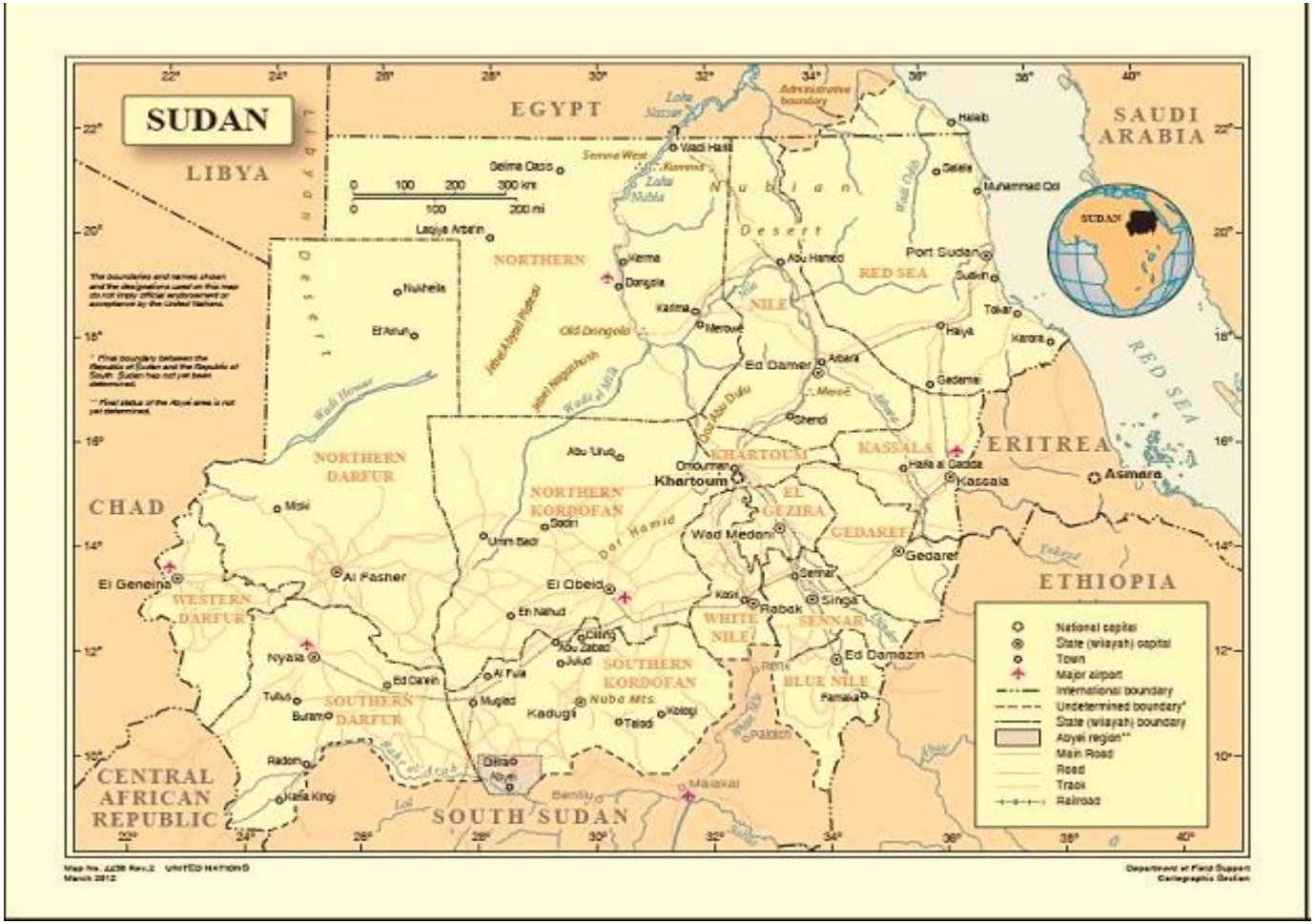


Figure 1-4 Map of Sudan (UN, 2012) Map No. 4458.

1.8.1 Cancer Service Provision in Sudan

Sudan established a National Cancer Control Programme in 1982 (Hamad, 2006); however, because cancer services are centralized, results from the programme are modest. In the year 2004, the government pledged provision of cancer care to all Sudanese patients without "out of pocket expenses". Cytotoxic chemotherapy used in cancer care is obtained according to the WHO Essential Medicines List (EML) which is developed in consultation with senior doctors in the field as well as the lead pharmaceutical advisory bodies of the country (WHO, 2007a).

At the time this study was conducted, two large cancer centres, both situated in the centre of the country, 180km apart, served the population (Abuidris, 2009). The largest of them is situated in the centre of the capital, Khartoum, close to other tertiary health services and teaching hospitals affiliated to the first medical school in Sudan (Khalil, 2013). The cancer centre was built in the late 1960s and, although it has been expanded, the number of patients presenting with cancer has increased 10 fold (Awadalla et al., 2007). This increase has not been matched by resources in terms of equipment, human resources or facilities (Elgaili et al., 2010). For example, the introduction of cytotoxic chemotherapy in the late 1980s has made a significant difference in delivery of care to patients, but these drugs are prepared on open benches in wards, exposing the process to considerable risk of errors.

Currently, the cancer centre in Khartoum delivers care to 7000-8000 patients each year (Abuidris, 2009;Ahmed et al., 2013) of which approximately 100 outpatients receive cytotoxic chemotherapy agents every day. The list of approved chemotherapy protocols at the cancer hospital is attached in Appendix 1. Other services include such as nuclear imaging and diagnostics, histopathology, radiotherapy, and palliative care services (Abuidris, 2009;Tanneberger, 2012).

In the shadow of the fragmented health system, the poverty of the inhabitants of Sudan, a literacy rate of 40-60% (Hamad, 2011;Mahaini, 2005) and the lack of cancer pathways, it is not surprising that most patients present to cancer services with advanced disease (Hamad, 2006;Hamad, 2011;Awadelkarim, 2012). Although research is lacking in health-seeking behaviour of Sudanese patients, some studies have revealed that there are multiple factors involved; personal, cultural, financial and access to care. Limited knowledge about cancer is probably a major reason because patients interpret the disease as non-sinister and initially seek treatment from traditional healers. Some research has identified that the social factors

such as ostracizing cancer and fear of becoming a burden on the family can be a deterrent to some patients, whereas in others it is mainly financial (Elgaili et al., 2010;Ibrahim et al., 2011).

Data from Sudan is somewhat different to cancer distribution in EMRO and European regions of the WHO, where lung cancer is the most common presentation (WHO, 2011b). Prostate cancer is more common among Sudanese men but the distribution among females was also similar to worldwide distribution where breast cancer is more common (Saeed et al., 2014). The most common cancers registered in Khartoum during 2009-2010 are shown in Figure 1-5.

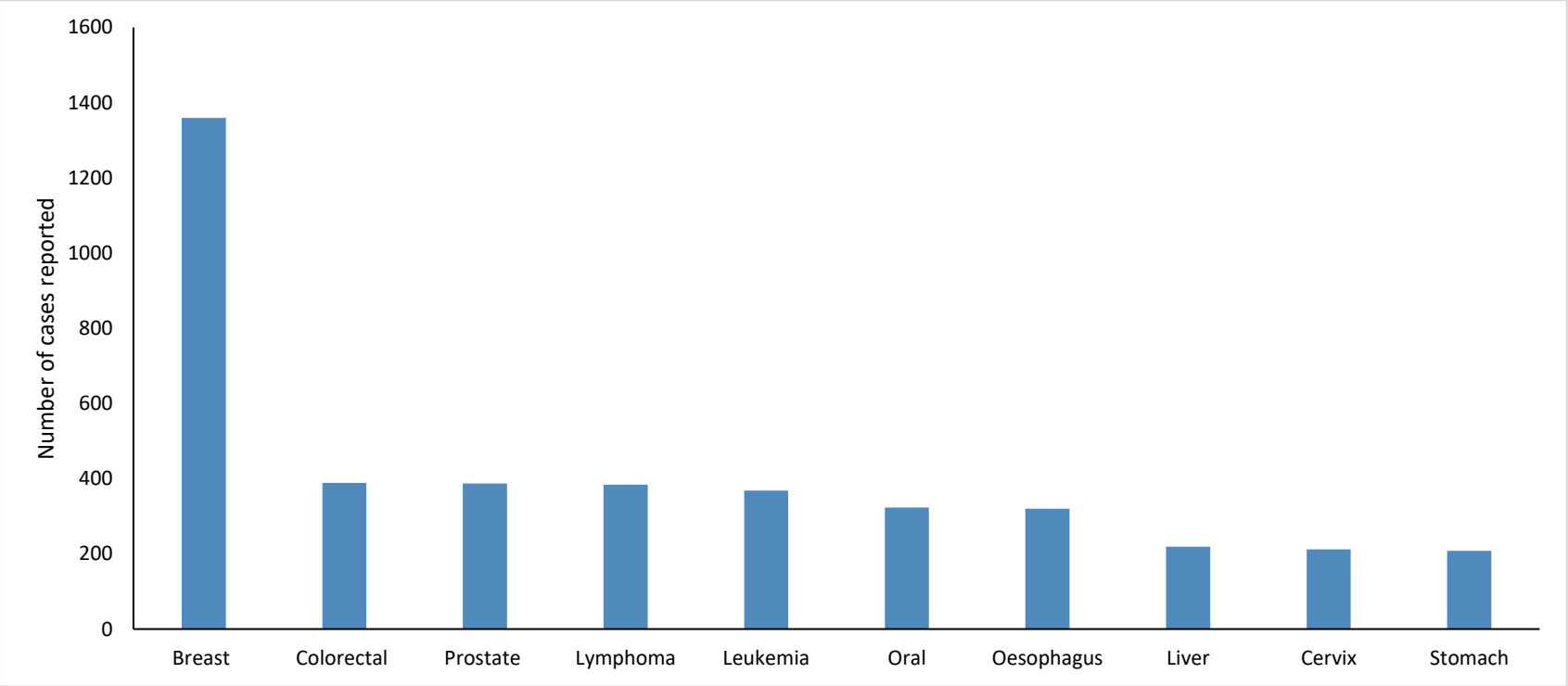


Figure 1-5 Top 10 most common cancers among adults aged 15+ in Khartoum during 2009-2010 (N=6224) (Saeed et 2014 p1078)

CHAPTER TWO-

2 OVERVIEW OF THE THESIS

2.1 Importance of this work

Evidence from the literature has shown that little research had been undertaken on medication errors in the EMRO region and there is no published evidence of research investigating the safety of cytotoxic chemotherapy.

This lack of evidence poses a problem when attempting to design interventions to improve the care of cancer patients in EMRO region. This research may be of importance when identifying key areas of interventions that need to be prioritised, particularly in a developing country where resources are limited.

The research presented in this thesis consisted of a mix of qualitative methods and quantitative methods, which are outlined in the current chapter. The qualitative methods entailed engaging HCWs at the cancer centre in interviews and focus groups, while the quantities methods consisted of observations on the administration of intravenous cytotoxic chemotherapy and collecting errors associated with the prescribing of those drugs.

Although the research programme was largely observational in nature and involved collecting data on standard practice at the cancer centre, a number of ethical issues important to the conduction of research were needed to be considered. The following section includes how these ethical issues considered and addressed.

2.2 Research questions and Hypothesis:

A number of research questions are the focus of this study

Q1: What do staff working at a cancer centre in a developing country know about safety culture?

Q2: What is the frequency and the potential causes of prescribing errors at a cancer centre in Sudan?

Q3: What is the frequency and the potential causes of intravenous administration errors at a cancer centre in Sudan?

Q4: What are the recommendations for practice resulting for the cancer centre in Sudan, in view of these findings?

Based on these questions, we can hypothesize that:

1. The patient safety culture, with respect to chemotherapy, in a cancer centre in Sudan is similar to that reported in the literature.
2. With regards to prescribing errors in a cancer centre in Sudan the category, frequency and potential causes are the same as those reported in the literature
3. With regards to administration errors in a cancer centre in Sudan, the category, frequency and potential causes are the same as those reported in the literature.

2.3 Description of thesis chapters

The first chapter of this thesis outlined the main findings from the patient safety movement with an emphasis on medication errors in particular those involving cytotoxic chemotherapy. Cytotoxics are considered by International Health and Safety bodies to be carcinogenic and mutagenic (Eisenberg, 2012;IARC, 2012), which creates considerable concerns for individuals exposed to these agents. This invariably includes healthcare staff who transport, prepare and handle these products. Thus, a review of the evolution of safety measures concerning the health and safety issues with regards to handling of cytotoxics was included in the first chapter. The chapter then presented the philosophical underpinnings for the research and finally, background information about the setting for this study (a large cancer centre in Sudan).

A preliminary analysis of 100 archived medical records at the cancer centre revealed that 21% of the records, had no age details, 56% had no tumour staging and 79% had no record of when symptoms started. The medical records were clearly deficient and therefore using retrospective chart review as a research method for identification of medication errors would have not provided sufficient findings. Previous work has shown that prospective study designs are more appropriate for identification of medication errors (Bates et al., 1995b). The following section provides a brief outline of the prospective methods used in this study (Figure 2-1).

The third chapter provides a description of a study that was undertaken to explore the safety culture at the cancer centre using the Manchester Patient Safety Framework (MaPSaF) (Parker et al., 2006). This was a preliminary study designed to provide an in depth understanding of the safety systems in place at the centre. Findings from this study helped in the development of subsequent work because it identified that safety systems were not in place at the centre and HCWs had limited understanding of safety culture and

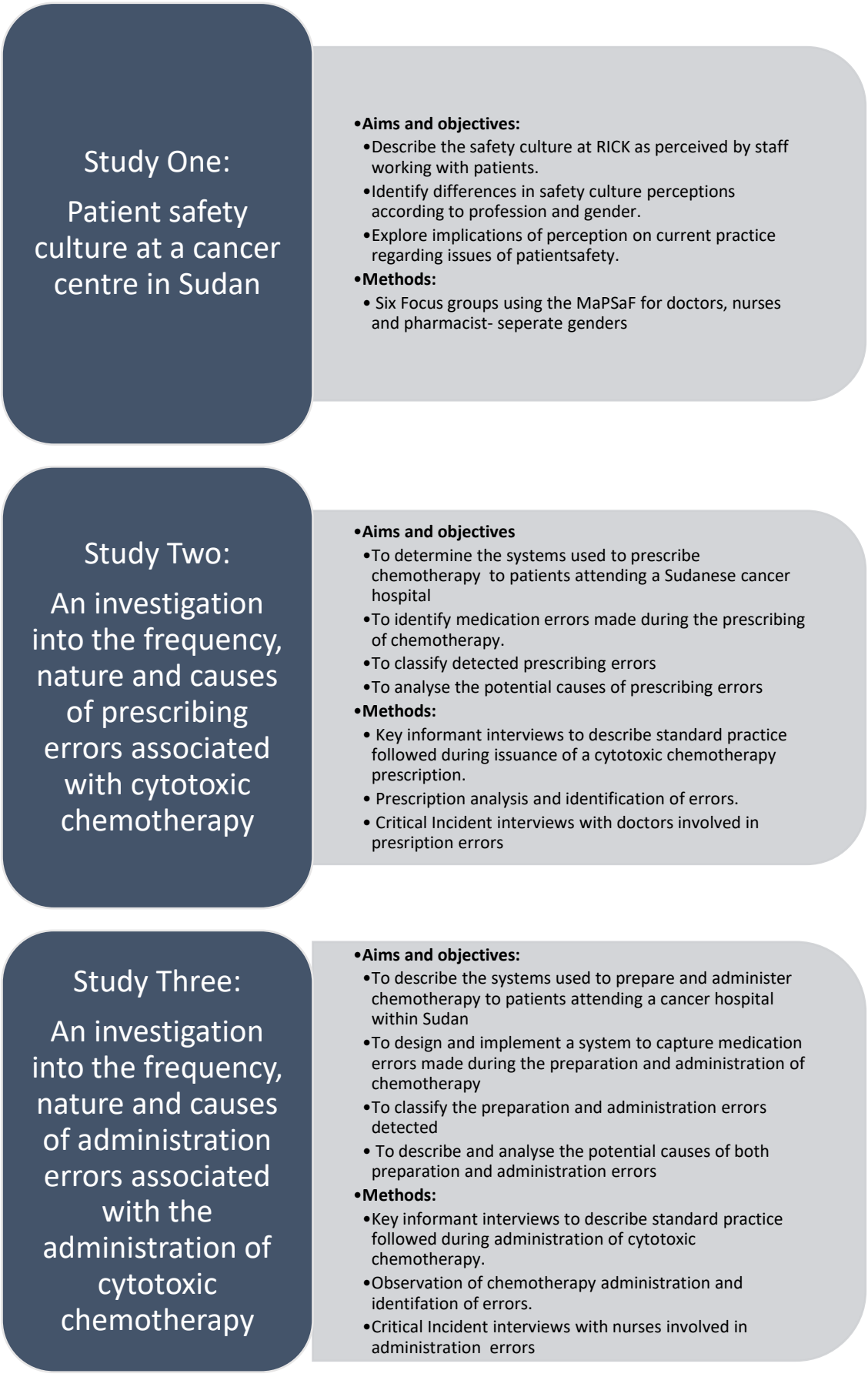


Figure 2-1 Overview of research presented in this thesis

safety systems. Furthermore, at the time, major changes had taken place at the centre and these included the development of a cancer protocols booklet approved by the cancer centre in order to standardise prescribing.

Evidence from the literature shows that medication errors in chemotherapy are associated mainly with the prescription and administration of these drugs and hence it was decided to focus on these two stages for the study.

The fourth chapter in this thesis provides an overview of prescribing error literature and contains a description of the work conducted at the centre to explore such errors. The work commenced by conducting key informant interviews with doctors to identify standard practice followed during issuance of a cytotoxic chemotherapy prescription. This was followed by an analysis of cytotoxic chemotherapy prescriptions and critical interviews with doctors involved in errors identified from the analysis. Finally, and due to small numbers recruited in the critical incident interviews, a focus group was conducted with doctors at the cancer centre, to identify the scope and nature of prescribing errors, from their perspective and how they are managed.

The fifth chapter in this thesis starts with an outline of intravenous administration error literature followed by key informant interviews to explore the standard practice involved in the administration of cytotoxic chemotherapy. Information from these exercises was used to inform an observation study of intravenous administration practices taking place on the chemotherapy day ward. Critical interviews were conducted with HCWs involved in the errors identified. This study was halted early because findings showed a considerably large number of errors relative to the incidence identified in the literature.

The last chapter provides a final discussion of the findings from the current research and links them to the current published literature. An outline of recommendation for practices and for further work in the area are also discussed.

2.4 Ethical and Cultural Considerations

This project complied with the research principles as described by the Sudan Medical and Scientific Research Institute (SUMASRI) (SUMASRI, 2008). An application was made to SUMASRI which comprised the following documents:

- Research proposal outlining all planned research activities.

- Participant information leaflets for each research activity in English and Arabic that contained the following information:
    - Background to the project
    - Objectives of the project
    - The criteria why they were chosen
    - Protection of their employment rights
    - Freedom to withdraw from the project at any time
    - Confidentiality of their responses
- Consent form in English and Arabic

Ethical approval was obtained in April 2011 prior to commencing data collection (Appendix 2).

Prospective research participants, for each of the three studies, were given a project information leaflet and two copies of a consent form by hand with a week to read and decide if they were willing to participate in the project. The participants were also allowed to ask questions, for further clarification. Prospective participants were asked to contact the researcher by phone or in person to agree to take part in the study.

Participants were entered into the study when they have provided voluntary consent. In developing countries, written and signed documents may be perceived as posing legal risks to participants (Bhutta, 2004). Previous research has shown that in situations where it was apparent that obtaining written consent was impossible verbal consent and tape recordings were substituted (Emanuel et al., 2004). In an attempt to encourage participation in this research and due to the sensitive nature of medication error discussions, participants were given the choice of any the following to be used as evidence that informed consent has been provided:

- Taped recording of consent
- Written consent
- Verbal consent documented by a third party

To maintain the confidentiality of the data obtained; observation notes, tape recordings of interviews and focus groups, transcripts, verbatim answers and evidence of informed consent forms will be stored in a locked cupboard for a period of 12 months after completion of the thesis and destroyed after the completion and dissemination of the

project. Anonymity was assured by assigning respondents unique nameless identifiers to prevent associations of responses to specific participants.

The information leaflet for each study stated the length of the research activity with explicit statements explaining the freedom to withdraw at any time. While risks are present in all research, the risks to participants in this research were minimal because anonymity of the data were maintained and therefore it, would be difficult for a third party to link information to the specific participants.

2.5 Research Team

The principal research team consisted of three members; the principal researcher, a translator and a moderator who helped with conducting the focus groups.

Apart from the principal researcher, the two other members of the research team had no working relationships with HCWs at the cancer centre. This was important to ensure the confidentiality of study participants. All members of the team were fluent in both Arabic (the language spoken in Sudan) and English.

The language used in conducting the interviews and focus groups was mainly the Arabic language because it was felt that although pharmacists and doctors may have good fluency in English, the use of their mother tongue in discussions would enable them to express themselves more clearly. It was necessary to translate some of the documents into Arabic language and more specifically colloquial Arabic because the majority of nursing staff had minimal formal education and hence were unable to understand long English sentences or even Classic Arabic. The person who acted as a translator was a senior university colleague who had some experience in translations but was fluent in both languages, written and spoken. He had other roles besides translation and his main responsibilities were as follows:

1- Listening to tape recordings of interviews and focus groups in order to verify transcripts.
2- Acting as a second translator to separately translate research documents from English to Arabic. These were:
    a. Focus Group Schedules.
    b. Interview Schedules.
    c. Participant Information Leaflets.
    d. Consent Forms.

3- Translate interview and focus group transcripts from Arabic to English.
4- Participating in meetings with the principal researcher to compare translations and provide a mutual agreement on the best context for the final translation.

Confidentiality of interviewees was maintained by choosing a translator from a different work setting and making sure that the transcripts were coded so as not to reveal their identity. Nonetheless, the translator agreed to keeping the information confidential because the identity of the interviewees and focus group participants could be revealed in the tape recordings when their names were mentioned which occurred on several occasions.

All three members of the research team understood the need for maintaining confidentiality during the course of this study.

2.6 Translation

Cultural adaptation of research tools (Brislin, 1970) was undertaken at the research design stage translating all written documents to be given to participants in Arabic language.

Brislin's model of back translation is considered the gold standard in cross-cultural research (Rennie et al., 2008;Klepstad et al., 2002;Brislin, 1970) and has also been used in medication error research (Chiang et al., 2006) .

This method is an iterative process whereby the forward translation stage is repeated until the back translated document resembles the original. It requires a different bilingual translator to translate the original document to the target language at each stage, followed by a back translation carried out without the individual seeing the original document. Each stage is evaluated by a group of translators and the process continues until the back translation resembles the original document. the approach would be essential for translation of validated research instruments.

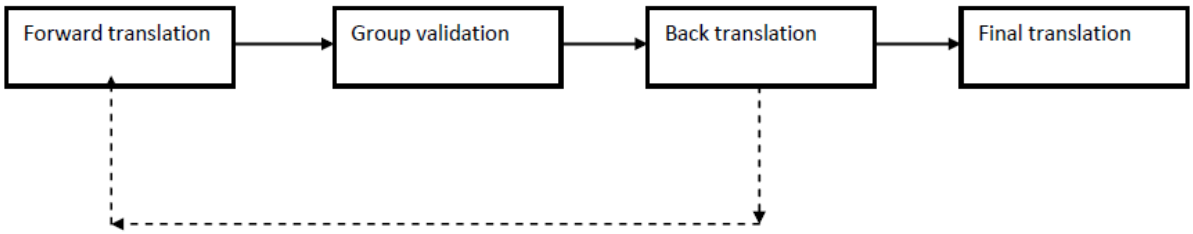


Figure 2-2 Rennie's Adaption of Brislin's Back Translation Model (Rennie 2008 p418)

Several authors have proposed modifications (see Figure2-2) to improve the efficiency of this model (Rennie et al., 2008;Jones et al., 2001). For the purposes of the current study, Rennie's adaptation of Brislin's model method was used for translation of validated study tools, PILs and consent forms. However, all the interviews and focus groups were conducted in Arabic and the verbatim answers required translation into English. This makes the exercise particularly time consuming specifically in the context of translating lengthy interview scripts within the time limitations of a PhD. Cross-cultural researchers have adopted more pragmatic approaches omitting the repetitive steps described by Brislin (Jones et al., 2011). One such approach was used in a Sudanese context and involved a single forward translation step (Baird, 2011). In order that a robust method was used in this research, Brislin's model was modified by omitting the back-translation step but group validation was used to ensure that the translated document was equivalent to the original document.

The translation team consisted of the researcher and one academic who were both fluent in Arabic and English languages. Arabic is the mother tongue of both the translators which is important because it ensures that cultural meanings of the words spoken during the interview are understood. The following process was adopted for each interview script:

1- The researcher and translator translated the verbatim script into English separately and simultaneously.
2- Differences between the two documents were compared and discussed at length to reach a mutual agreement on the final translation.
3- Notes and changes were made to each transcript before producing the final version.

2.7 Research Challenges

During the course of this study, a number of challenges were experienced, mainly because the concept of studying medication errors in a country where very little previous work had been undertaken, was perceived as a potential threat to participants. This was evident by the response of HCWs to this project. Although, when approached initially, prospective participants showed interest, there was poor attendance at pre-arranged appointments for focus groups and interviews. Some HCWs failed to attend appointments and sometimes their mobile phones were switched off and they were difficult to contact. In other situations, and perhaps also due to the busy schedule of work at a tertiary cancer centre, it was necessary to re-schedule interview and focus group appointments many times. The lack of interest expressed and the reluctance of HCWs to participate in discussions about medication errors was not unique to this study. These issues were demonstrated clearly in the early medication error research which showed considerably low error rates from nurse and pharmacist incident reporting when compared to chart review (Bates et al., 1993).

Most nurses who participated in this research showed reluctance to sign written consent forms and expressed that their participation in the study would be on the condition that this requirement was waived. Thus, the ethical requirements necessary in the UK, were modified as explained above in the ethical considerations section.

Towards the final stages of the research, data collection was halted because a chief administrator expressed concern about the dissemination of the study findings. Although this was a considerable set back, because prior ethical clearance was obtained from a Ministry of Health (MoH) recognized body. A request was made that the administration from the cancer centre should write a letter to the principal researcher explaining why they considered data collection should be halted. This letter was never received and data collection continued allowing successful completion of the study. Following discussions with key personnel from the Ministry, research supervisors and colleagues at the cancer centre, a decision was made to continue data collection.

CHAPTER THREE

3 AN ASSESSMENT OF PATIENT SAFETY CULTURE

3.1 Introduction

There is consensus among national and international authorities about the importance of a positive safety culture in healthcare (Department of Health and Children, 2008;Kohn, 2000;WHO, 2004b). Both health safety researchers (Leape et al., 2000;Vincent et al., 2000), and industry safety researchers (Helmreich, 2000) have also confirmed its importance. Guidance published to enable healthcare institutions to achieve patient safety have emphasized that building a Patient Safety Culture (PSC) is essential (NPSA, 2004b;IOM, 2004). One example is the former UK NPSA, who produced *The seven steps to patient safety* which identified building a safety culture as the first step towards implementing patient safety strategies (NPSA, 2004b).

Measurement of safety culture is instrumental in providing an understanding of how an organization views and responds to all aspects of safety as well as serving to highlight areas that require improvement (Nieva et al., 2003). This has important relevance to the current study because to our knowledge there has been no published study on the safety culture in healthcare institutions in Sudan. Moreover, poor safety practices when dealing with complex patients, such as those with cancer, is likely to have more detrimental consequences than among patients with fewer medical needs (Hofmann et al., 2006). It can be argued that, in the chemotherapy unit, under study, the patients are considered complex for several reasons; 1) they present with advanced disease (Hamad, 2006) and have a high risk of organ impairment, 2) they are receiving potentially toxic substances (Gilbar, 2001) and 3) finally, intravenous medicines are prepared in uncontrolled environments on open benches in ward areas, placing both nurse and patient at considerable risk for safety (Joshi, 2007). A study of the PSC in this setting would provide useful insight into the nature of safety systems adopted by HCWs and present an opportunity for them to engage in discussions regarding safety.

This chapter begins with a review of a number of PSC tools that are commonly used in healthcare. The advantages and limitations of their use are discussed. The aims, methodology and results of a qualitative safety culture assessment at a cancer hospital are then reported. The discussion section presents a comparison of the results with existing literature and their impact in the context of a cancer centre in a developing country.

3.2 Definition of Safety Culture

Safety culture is the shared values, assumptions and beliefs that an organization holds, whereas safety climate encompasses the measurable components of these values manifested in the behaviour, perceptions and attitudes of employees (Colla et al., 2005). The latter being a component of the former (Thomas et al., 2005). In simpler terms, culture could be thought of as the personality of the group, while climate is the mood (Cox et al., 1998).

In the literature, the two words have been used interchangeably in many contexts but although researchers have agreed that both can be regarded as being similar, the tools used to measure culture are fundamentally different from those measuring climate. For example, safety climate can be readily deconstructed into quantifiable dimensions or concepts because it measures the attitude and behaviours shown by employees. This, however, does not apply to culture, which is not so easily shaped (Flin, 2007) and involves the dynamic processes that are deeply embedded and are continuously being shaped within the organization (Guldenmund, 2000). Culture is more suited to ethnographic research which aims to describe and understand rather than quantify (Guldenmund, 2000). However, because questionnaires are efficient methods for data collection, they have become the focus of the development of safety culture research (Flin et al., 2006;Colla et al., 2005;Singla et al., 2006).

3.3 Overview of Safety Culture Tools

Since the publication of recommendations by healthcare authorities, urging healthcare institutions to adopt a safety culture (Department of Health and Children, 2008;Kohn, 2000;WHO, 2004b), a diverse range of assessment tools have been developed to evaluate both safety culture and safety climate (Ashcroft et al., 2005;Blegen, 2005;Connelly, 2005;Fleming et al., 2008;Ginsburg et al., 2009;Kirk et al., 2007;Pronovost et al., 2003;Sexton et al., 2006 ;Singer et al., 2003;Sorra et al., 2008;Kho et al., 2005).

The UK based Health Foundation (2011) published a review that provides an overview of some of these tools for use within the NHS and lists over twenty tools commonly used in healthcare settings.

Most of the tools identified are quantitative, and use a 4 or 5 point Likert scale for response (Singla et al., 2006). Many have originated in high risk industries such as oil drilling and

aviation (Guldenmund, 2000) but have been later modified for use in healthcare (Flin et al., 2006).

These tools may be used to assess and assign safety culture scores to hospitals as a whole, separate units or healthcare teams (Nieva et al., 2003). Safety culture tools have been used for a number of purposes. These include; assessment of patient safety culture (PSC), improving employee involvement, monitoring the impact of healthcare interventions, external and internal benchmarking and the extent that regulatory requirements are fulfilled (Nieva et al., 2003;Fleming, 2005). Despite these similarities, these tools vary tremendously. Flin and colleagues (2006) reviewed twelve studies that measured PSC and argue that PSC has been misapplied, mainly due to a misunderstanding of the important criteria required to ensure the robustness of measurement tools. For instance, some tools have been developed for local use within individual hospitals without taking into consideration requirements for survey design, such as counterbalancing negative and positive statements (The Health Foundation, 2011). Whereas others have been developed in industry, where they have been extensively tested and used, and were later either used in their original format or modified for use in healthcare and then further modified for use in specific healthcare settings. Such tools are not always transferable between different industries because many challenges can be encountered due to the differences among the settings (Flin, 2007). Most importantly, the differences between healthcare and industry lie in the context where safety culture is applicable. Safety in the healthcare environment involves both patient and worker; patients are unpredictable and team relations between and among different disciplines are more flexible than in industry (Flin et al., 2006). Similar arguments have been proposed in industry where an instrument developed in one industry may not be directly transferable to another (Cox et al., 1998). These findings were confirmed in other reviews of PSC tools (Colla et al., 2005;Singla et al., 2006).

Further controversy exists regarding the use of terminology because when these tools were constructed researchers have used the terms "safety climate" or "safety culture" interchangeably (Flin et al., 2006). Flin and colleagues (2006) reported a number of PSC tools that lacked theoretical underpinning, whereas others who have published theoretical underpinnings used a number of different safety culture theories (Fleming, 2005).

Culture tools have mostly been designed to measure specific dimensions of culture and each tool had its unique dimensions, but some common themes were identified such as leadership, communication and teamwork (Singla et al., 2006). Other dimensions added

include safety systems, risk perception, job demands, reporting, safety attitudes, personal resources and organizational factors (Flin et al., 2006).

A number of these tools have been developed without psychometric testing that describes the validity and reliability (Flin et al., 2006). Some researchers have either not published their results of psychometric testing (Singla et al., 2006), or have published psychometric criteria below acceptable levels (Kho et al., 2005).

When administered to healthcare staff, these tools have had variable response rates, ranging from 26% to 83% (Pronovost et al., 2005), and have sometimes proven to be invalid. There are several reasons to explain this observation. For example, a tool used in the USA may not necessarily be applicable to a UK setting and a tool used in an ICU setting may also lack validity when applied to a general medicine ward. Furthermore, Kho and colleagues (2005) argued that a tool may not necessarily measure the same constructs when used in different countries with their own unique health systems, team hierarchies and national cultures. They based these observations on a study where they used three different instruments, originating from work by Sexton and colleagues, on ICU staff in Canadian hospitals. The psychometric testing revealed major flaws with one of the instruments, showing the level of internal consistency to be lower than acceptable (Kho et al., 2005).

These disagreements between PSC tools stem from the original concept of organizational culture, which is viewed as an abstract phenomenon, and hence gives the researcher the freedom to define and operationalise it according to their analysis and setting. Furthermore, organizational culture theorists vary considerably in their view, some conceptualising it as observable practices and attitudes whilst others regard it as unconscious basic assumptions (Guldenmund, 2000). This has resulted in non-uniformity in the type of research used to study PSC where both quantitative and qualitative tools have been developed (Flin et al., 2000), because some see it as a holistic concept whereas others are more reductionist and see it as a group of measurable attitudes (Guldenmund, 2000).

3.4 Patient Safety Culture Tools

The Health Foundation (2011) published a report on tools used in measuring PSC to help NHS hospitals in selecting the most applicable and robust tool. Although not a systematic review, it nevertheless collated a number of tools, summarized their use in healthcare and listed their advantages and disadvantages. It identified the five most commonly used as:

The Safety Attitudes Questionnaire (SAQ), the Hospital Survey on Patient Safety Culture (HSOPSC), the Manchester Patient Safety Framework (MaPSaF), the Patient Safety Climate in Healthcare Organizations (PSCHO) and the Safety Climate Survey (SCS). A systematic review conducted by the European Network for Patient Safety (EuNetPaS) recommended that three of the above mentioned tools (SAQ, HSOPSC and MaPSaF) should be used in member states for measurement of safety culture (ESQH, 2008). The reasoning behind this recommendation lies in the rigour with which these tools were developed, and their robustness was shown when they were used in European Union member states with acceptable results. Moreover, the WHO (2004) and Flin and colleagues (2009), recommend the use of the SAQ and the HSOPSC.

The following section will list the history, development, uses, advantages and limitations of some of these tools (Table 3-1). This is a review of nine tools which includes the five most commonly used tools and briefly discusses less commonly used tools in order to highlight some of the issues complicating the comparison and generalisability of safety culture tools. Table 3-1 shows the different number of dimensions included in each tool. They will include tools that have been developed in a specific field of healthcare such as pharmacy (Ashcroft et al., 2009), a tool that was developed specifically to measure culture in a setting different to western culture (Matsubara et al., 2008), a tool that had to undergo modification to allow its wider use in healthcare (Pronovost et al., 2003), and lastly a tool developed to measure one safety aspect (Gershon et al., 2000).

3.4.1 The Safety Attitudes Questionnaire (SAQ)

The Safety Attitudes Questionnaire (SAQ) originated from safety culture research in aviation and is a modified version of the Intensive Care Unit Management Questionnaire (ICUMQ) (Sexton et al., 2000) which was based on the Flight Management Attitudes Questionnaire (FMAQ). The FMAQ was developed to measure crew members' attitudes towards certain safety aspects such as teamwork, speaking up, leadership, communication and collaborative decision making. When developing the SAQ, items from the FMAQ valid for use in healthcare were retained and others removed or modified accordingly. The final 40 item questionnaire focused on team work and working conditions. It consists of six dimensions (Table 3-1) and uses a 5-point Likert scale to determine the level of agreement of responders (Sexton et al., 2006).

The SAQ was the first PSC tool to be extensively evaluated for reliability and validity. Sexton and colleagues (2006) surveyed 10843 healthcare staff from different disciplines and levels in 203 healthcare settings; in the UK, the USA and New Zealand. The tool had good psychometric results (Raykov's coefficient, 0.90) with acceptable multilevel confirmatory analysis (Sexton et al., 2006). The authors compared findings from 203 clinical areas and found substantial variability in team work climate, safety climate, job satisfaction, stress recognition and working conditions and concluded that the SAQ is a useful instrument for benchmarking.

The SAQ has been used for several purposes. It was one of the first tools to be used for inter-hospital as well as intra-hospital benchmarking in comparison with industry, it was also used for testing associations with improvements in safety culture and reporting outcomes, process measures and patient safety outcomes (Sexton et al., 2006;Colla et al., 2005). It has also been used in a pre- and post-intervention study to improve patient safety in ICUs across Michigan state (Pronovost et al., 2008).

In an interventional study, researchers in the US collected baseline teamwork climate scores and adherence to evidence-based interventions in ventilated patients among ICU staff and implemented the Comprehensive Unit Based Safety Program (CUSP) intervention (Pronovost et al., 2008). Post intervention testing measured these outcomes a year later. The CUSP is a six-step iterative safety intervention programme that improves patient safety culture by educating healthcare teams, increasing awareness and providing them with interventional toolkits targeting areas of poor patient safety. The study reported an improvement in teamwork climate from 17% to 46% and an improvement in the inclusion of chlorhexidine scrubs in the ventilator kits, but no measurable improvement in patient outcomes. The authors attributed this to a number of reasons; variations in clinical practice and in definitions of ventilator associated pneumonia and catheter related blood stream infections (Pronovost et al., 2008). The findings from this study support the view that although the introduction of safety practices into an organization may have improved certain aspects of culture, true culture change requires that interventions be sustained for periods of time longer than one year.

The SAQ has many positive attributes. It uses Vincent's framework for analysing risk and safety and Donabedian's conceptual model for assessing quality (Sexton et al., 2006) and is available in the public domain for non-commercial use (Flin et al., 2009). It has also shown acceptable psychometric properties and has been used in PSC research in ambulatory care

(Holden et al., 2009), intensive care settings (Huang et al., 2010), translated to Turkish (Kaya et al., 2010), Chinese (Lee et al., 2010), and Norwegian (Deilkas et al., 2008) and adapted for regulatory authorities in the pharmaceutical sector (McCarthy, 2009). This demonstrates both reliability and validity (Allen et al., 2010;Pronovost et al., 2005).

One of the major limitations in the use of the SAQ is the variable response rate, which can sometimes be as low as 29% or as high as 83% (Pronovost et al., 2005). In a study conducted by Allen and colleagues, among members of staff in two maternity units in Australia, only 29% of participants responded. This led the authors to disregard the findings as unreliable and to recommend that safety culture would be better measured using qualitative studies.

3.4.2 Hospital Survey on Patient Safety Culture (HSOPSC) -US Agency for Healthcare Research and Quality

The Hospital Survey on Patient Safety Culture (HSOPSC) was developed under contract for use by the US based Agency for Healthcare Research and Quality (AHRQ). The development of this tool included a thorough literature review on patient safety, safety culture and climate, organizational factors, medical error, error reporting and pre-existing tools on safety culture (Sorra et al., 2004). Key dimensions were identified and used to derive the original survey tool, which was subsequently reviewed and validated by hospital staff and researchers (Sorra et al., 2004). The final version was subjected to piloting and psychometric analysis by administering it to 1437 staff from 21 hospitals across the US and the best items and scales were retained.

Unlike the SAQ, which is focused primarily on teamwork, the HSOPSC extends its emphasis to management commitment to safety, handovers and transitions (Singla et al., 2006). It is designed to measure seven, unit level aspects of patient safety culture, three hospital level aspects and three outcomes, using 42 questions (Table 3-1).

In further research, Sorra and Dyer (2010) intended to confirm the original psychometric evaluations and tested the tool with over 50,513 HCWs from 331 hospitals in the US. The results provided acceptable psychometric properties on all dimensions with the exception of the staffing composite, which fell below the acceptable level at 0.37 (Sorra et al., 2010). The analysis found a strong relationship between overall perception of safety and management support for patient safety but a surprisingly weak relationship between non-

punitive culture and adverse event reporting (Sorra et al., 2010). The survey had an average response rate of 55%, which was considered acceptable.

The tool has proven validity because it was used to evaluate PSC in adult critical care units (Armellino et al., 2010), and nursing homes (Castle et al., 2006). It has been translated into Italian (Bagnasco et al., 2011), Turkish (Bodur et al., 2009), Chinese (Chen et al., 2010), Japanese (Ito et al., 2011) Dutch (Hellings et al., 2010) and Arabic (El-Jardali et al., 2010). In the Middle East, the tool was tested in Saudi Arabia (Alahmadi, 2010) in its original English format as well as in Arabic (El-Jardali et al., 2010).

Although the HSOPSC has been developed and mainly used in inpatient and hospital settings, it has also been used in primary care settings (Bodur et al., 2009). The main weakness of this tool, similar to the other key PSC tools, is that it identifies weaknesses within PSC but not their cause. One of the other weaknesses of this tool is a consistently low response rate of less than 50% (Armellino et al., 2010). In the study by Armellino et al (2010), the HSOPSC was distributed among 257 registered nurses within critical care in a US hospital. The questionnaire response rate was low at 40% but the authors inferred that this low response rate could be explained by the low safety culture score (21.09%) and the low error reporting rate (62.5%).

Criticisms of the HSOPSC point to its weak reliability in assessing staffing dimensions. For example, when used in Lebanon among 12,250 healthcare staff from 68 hospitals, with a 55% response rate, the staffing dimension had the weakest correlation with the outcome of adverse event reporting (El-Jardali et al., 2011). The highest positive scores for safety dimensions measured were for teamwork (82.3%), hospital management support (78.4%) and organizational learning (78.3%). The strength of reliability testing was doubtful because it varied between 0.431 and 0.61 for communication and 0.423 and 0.57 for staffing among different healthcare teams. The authors published their translation of the survey technique, which was not based on any known method of cross cultural research, thus having the potential to introduce construct weakness to the study as predicted by the study authors (Sorra et al., 2004). Although the study sample originally included doctors and pharmacists, the respondent group consisted mainly of nurses and clerical staff. These results were similar to a Saudi study which used the HSOPSC questionnaire in its original format without translation. The survey was distributed to 2580 HCWs from 13 Saudi hospitals which have demonstrated patient safety initiatives in place, from both the private and public sectors (Alahmadi, 2010). The hospitals had good scores for learning (87%), teamwork within units

(84%) and feedback about errors (77%) but it was interesting that teamwork across the hospital was weak (27%). Other areas which required improvement and showed poor scores on the patient safety scale were non-punitive response to errors (22%) and staffing (22%). Response rate in this study was similar to others with a poor response rate below 50%. The authors aggregated all the findings together and there were no comparisons among hospitals, hence it was not clear if there were associations between particular weaknesses and specific hospital characteristics (Alahmadi, 2010). For example, the Lebanese study showed overall patient safety scores were higher in smaller hospitals (El-Jardali et al., 2010).

The HSOPSC has now developed to be a widely-utilized tool in research because psychometric testing has shown its reliability and validity and hence its robustness (Singla et al., 2006;Sorra et al., 2010). It encompasses all the issues pertinent to measuring PSC, as detailed by Reason (1997). A toolkit for general use and access with details of the tool development are available in the public domain via the AHRQ website (Sorra et al., 2004).The HSOPSC has been recommended for use by the WHO in their High 5s project to achieve reductions in high risk patient safety problems. They recommend participating hospitals use the tool to measure baseline patient safety culture and monitoring of changes over time (Sorra et al., 2010). Consistently low rates of response have been frequently compensated for by inclusion of a large sample for the survey.

3.4.3 The Safety Climate Scale

One of the less well developed tools was the Safety Climate Scale, which is a 10 item tool, using a 5 point Likert scale, derived from safety culture studies in aviation, and focuses on leadership and employee commitment to PSC, adverse event reporting and understanding of systems in accident causation (Pronovost et al., 2003). The tool was first used in healthcare to compare the attitudes towards error, stress and teamwork among healthcare staff working in operating theatres and ICU units across five countries in comparison to staff in aviation in the same countries (Sexton et al., 2000). The study used a disproportionate number of aviation staff (30,000), mainly cockpit crew, in relation to healthcare staff (1033); mainly doctors and nurses. As anticipated cockpit crew, coming from a longer history of safety, had better safety scores than HCWs. For instance, pilots were least likely to deny the effects of fatigue on performance (26%) compared with consultant surgeons (70%). More than 90% of aviation staff and anaesthetists rejected steep hierarchies in comparison to

55% of consultant surgeons. Safety culture scores varied among different healthcare teams with doctors (77%) having higher perceptions of good teamwork than nurses (40%).

The tool has been combined with other PSC scales because it lacks dimensions related to human factors such as teamwork and communication, focusing on employee and leadership perceptions of a strong organizational commitment to patient safety (Pronovost et al., 2003). In order to include the human factors, it was combined with the SAQ, and administered to midwifery staff in Australia, but the study was limited with a less than desired response rate of 28% (Allen et al., 2010). The tool was piloted and refined by Pronovost and colleagues (2003) but psychometric testing was not reported. The authors surveyed managerial clinical staff, clinical staff and clerical staff from wards, clinics and departments with a response rate of 82% (Pronovost et al., 2003), better than the HSOPSC (Armellino et al., 2010) and SAQ (Pronovost et al., 2005). Unlike findings from other studies (Sexton et al., 2000), this study revealed lower perceptions of safety culture among doctors than nurses. For instance, 84% of nurses perceived encouragement from management to report errors, whereas 54% of doctors perceived this to be true. Likewise, 46% of doctors and 86% of nurses indicated that they were aware of the proper channels for safety incident reporting. The absence of validity and reliability testing in published reports, together with the tool's limited scales, have prevented further use of this tool.

3.4.4 The Safety Climate Survey (SCS)

Given that the Safety Climate Scale had limited utility in PSC research, researchers submitted it to further development by adding more safety performance composites from aviation. The new tool, the Safety Climate Survey (SCS), consisted of 21 items using a 5 point Likert scale.

The SCS has been used in safety culture research as the sole research tool to assess the impact of executive walk rounds on patient safety culture among healthcare staff in a tertiary care hospital (Thomas et al., 2005), as well as in ICU settings (Kho et al., 2005) and in renal dialysis (di Benedetto et al., 2011).

Thomas and colleagues (2005) used the SCS in a "before and after" controlled study to assess the impact of executive walk rounds (EWRs), in all clinical units of a US tertiary care hospital, on staff safety culture. The published report of this early development work lacked psychometric testing (Thomas et al., 2005) which was separately conducted by Kho and colleagues (2005) among staff from four ICUs in Canada .

Thomas and colleagues (2005) used the tool to evaluate safety culture changes among nurses after an intervention which involved limited exposure to EWRs. The authors conducted a baseline study of PSC among 1119 healthcare providers from different hospital units such as pharmacy, radiology, nursing, physical therapy and dieticians. They randomised 23 hospital units, 12 to control group and 11 to EWRs, which consisted of 3 four-weekly 30-60 minute meetings conducted by a team of four executives from the hospital, in which all personnel from the hospital unit were invited and engaged in a discussion of issues pertinent to patient safety and the role of leadership in improving patient safety. After three months, the survey was repeated on the 23 units but results revealed no change for patient safety for all health providers except for nurses, who composed 50% of the sample. Nurses in the EWR intervention group (72.9%) had higher safety scores than those in the control group (52.5%). The results of this study, although showing the tool can detect culture changes, suggest that as the tool was originally developed for use among doctor and nurse teams it may not be valid for use within other healthcare teams such as pharmacy and physiotherapy. Moreover, the study period was too short to detect significant changes in culture.

Kho and colleagues (2005), using their experience from previous work to develop the PSC questionnaires, subjected the tool to psychometric analysis and administered it to 427 staff from four ICUs in Canada. The tool showed acceptable internal consistency (0.86), test re-test reliability (0.92). The authors reported similar safety culture perceptions among all teams of frontline staff in the four ICUs but higher perceptions among managers (Kho et al., 2005).

Although the Safety Culture Climate Survey was endorsed by the Institute for Healthcare Improvement (Kho et al., 2005) and was once available in the public domain, it has subsequently been removed, probably because it tests one construct only and is currently outdated (The Health Foundation, 2011).

3.4.5 The Patient Safety Climate in Healthcare Organizations survey (PSCHO)

Singer and colleagues (2003 and 2007) developed the Patient Safety Climate in Healthcare Organizations survey (PSCHO) as part of a Stanford based, patient safety research project, sponsored by the US based Agency for Healthcare Research and Quality and run by the Patient Safety Consortium which consisted of 105 hospitals from the USA. The tool, which is also known as the “Stanford Instrument” (Fleming, 2005) was constructed based on a

literature review of five safety climate surveys developed for High Reliability Organizations (HROs) such as nuclear power stations, aircraft carriers and aviation control systems (Weick et al., 2008). HROs are complex organizations which, despite of working under extreme hazard and high risk of error, maintain a high record of safety (Roberts, 1990), by being grounded in a state of collective mindfulness that makes all staff highly alert to details that may indicate danger.

The original five tools used in constructing the PSCHO were; the Naval Aviation Command Safety System Survey, the Operating Room Management Attitudes Questionnaire, the Anaesthesia Work Environment Study, Risk Management Questionnaire and Safety Orientation in Medical Facilities (Gaba et al., 2003), none of which were considered suitable in their original format because they were either not developed for healthcare or not subjected to rigorous survey administration and psychometric analysis (Singer et al., 2003). The authors identified a number of dimensions from these surveys that were suitable for tailoring a tool valid for use in healthcare organizations. The PSCHO was subjected to rigorous piloting that initially focused on feasibility of the tool, resulting in a reduction from 122 to 38 items covering nine dimensions (see Table 3-1), in addition to items that are designed to capture demographic and background data (Singer et al., 2003;Singer et al., 2007). Including demographic details is uncommon in other PSC tools but was thought to be important by the authors because they considered that PSC may be affected by such characteristics.

The tool was used to evaluate safety culture among 6312 hospital employees from senior management, doctors and other employees from a number of hospitals across California (Singer et al., 2003). The study used an unusual weighting to their sampling by including all doctors, all senior administration staff and 10% of other employees, justifying this with findings from previous studies that showed poor response rates among doctors. The study findings were consistent with other PSC research (Sexton et al., 2006 ;Kho et al., 2005) because it was shown that senior managers had more favourable perceptions regarding safety climate than did clinicians, and nurses had the least favourable perceptions. These findings were confirmed in a later study which included 35,370 hospital employees from 92 US hospitals (Singer et al., 2009b). The published report assessed feasibility of the tool rather than its psychometric analysis and lacked an account of the theoretical underpinnings. Although the authors reported that the tool was feasible in measuring PSC the response rate of 47% may indicate low face validity or generally poor safety culture

rather than the justification suggested for poor response by doctors because of busy work schedules.

Results from this study were compared with safety climate among US naval aviation corps (Gaba et al., 2003), using a separate tool utilized in the initial construction of the PSCHO and shares with it 23 common items . The response rate among the naval corps was nearly double that of hospital personnel (80% vs 47.7%). The authors analysed the common 23 items between the two tools and revealed that naval corps showed less negative perception of safety culture than hospital personnel (5.6% vs 18%) but had similarities in terms of their mutual belief of the high level of and commitment to safety by their individual organizations. Both groups also showed similarities in their concern for safety when resources or experienced personnel are compromised, but HCWs showed more concern. The administration of the survey in the naval corps was carried out over three years whereas in the hospital over six months, which may explain the increased response rate. The choice of naval corps may not be entirely successful in comparative research with medical and hospital personnel, who have totally differing cultures. Naval corps traditionally have a high culture of submission and obedience whereas hospital personnel have more freedom and flexibility in their own decision making (Gaba et al., 2003).

In a later study, Singer and colleagues (2007) subjected the tool to psychometric analysis by administering it to 42,249 individuals employed at 105 hospitals in the US with a 51% response rate. The study recruited participants from all disciplines and hierarchies within hospitals in the USA as part of a project run by the Patient Safety Consortium, which was formed specifically for this project. They asked HCWs to rate safety issues according to three levels; the individual, the unit and the organization (Table 3-2). Researchers reported psychometric analysis varied according to the dimensions measured, with low reliability for the learning dimension, Cronbach alpha score from 0.5 to 0.7 (Singer et al., 2007).

The PSCHO was used further to evaluate the impact of a safety intervention among nurses in Canada (Ginsburg et al., 2005), compare differences between healthcare teams in the US (Cooper et al., 2008;Singer et al., 2009b) and to test the association of organizational culture and patient safety climate (Hartmann et al., 2009).

Although previous studies showed limited changes when comparing PSC in “pre and post” interventional studies, nevertheless Ginsburg and colleagues (2005) attempted to evaluate the impact of an educational intervention on patient safety scores among nurses in leading clinical roles from two Canadian teaching hospitals, using non-equivalent control groups

(Ginsburg et al., 2005). The educational intervention was designed to address adverse events literature, human error, patient safety tools and the importance of human factors. A sample of 356 nurses were invited to take part in the study by completing the baseline safety climate questionnaire (PSCHO). They were then invited to attend the educational workshop which lasted six months. Nurses from the original cohort who did not attend the workshop were given the post study questionnaire to complete immediately after the workshop, with a 69% response rate. Nurses in the intervention group were asked to complete the questionnaire four months after completion of the educational intervention. Although a statistically significant ($p<0.001$, chi-square test) change was seen in valuing safety in the intervention group, no significant changes in other dimensions were detected. A decrease in the ratings of safety in the control group over a ten-month period was reported. The non-equivalent control group study may have introduced selection bias where nurses who originally had safety concerns were recruited. Similar to other PSC research (Thomas et al., 2005), the ten month period was barely long enough to permit significant changes in culture which is considered strongly embedded and difficult to change (Ginsburg et al., 2005).

Using a similar sampling frame to their previous studies, Singer and colleagues (2009) surveyed 35,370 hospital employees from 92 US hospitals. The findings were similar to previous work by these researchers with employees, where 17.1% of the responses from hospital employees indicated a negative perception of safety climate. This varied according to hospital, area of work and team. Employees in the emergency department had 18% more negative responses in their perception of patient safety. Among teams, nurses showed more negative perceptions compared to doctors. However, this finding was not applicable to all dimensions as nurses showed 24% higher negative perceptions of safety than doctors in terms of formal recognition of safety and 21% higher with regards to unit support. Doctors had higher negative perceptions with regards to fear and blame. Among the same discipline, ED nurses had 80% more negative perceptions of safety culture (Singer et al., 2009b). This study demonstrated the feasibility of measuring difference within and among healthcare teams and areas of work and showed differences according to discipline. Another study demonstrated that the tool can also identify difference due to team hierarchies (Hartmann et al., 2009).

The PSCHO was used to test the association between a strong organizational culture and patient safety climate at Veterans Health Associations (VA) hospitals in the US, a group of hospitals that comprise a significant part of the US health system (Hartmann et al., 2009).

The tool was administered to 9,250 staff, using Singer's sampling frame, at eight VA hospitals, with a 50% response rate similar to previous studies. The study revealed that hierarchy was related to poor safety climate and higher levels of group and entrepreneurial culture were associated with higher safety climate scores. Although the study found strong associations between safety climate and organizational climate, the effect on actual patient safety outcomes could not be accurately inferred.

This tool had been tested extensively, mainly in the US but generally restricted to North America, and included large numbers of participants. Response rates with this tool have been consistently lower than 50%, with the exception one study in Canada (69%) and even with reminders and repeated mailings did not improve above 50% (Singer et al., 2009b).

3.4.6 The Manchester Safety Patient Framework (MaPSaF)

This Manchester Safety Patient Framework (MaPSaF) provides a qualitative approach the application of PSC measurement which is unique among other tools that are primarily quantitative. The Manchester Patient Safety Framework was developed for research into PSC by Manchester University (Parker, 2009;Kirk et al., 2007). It was based on Westrum's typology of safety culture which proposes that safety culture follows a natural progression towards ultimate safety and that information flow across the organization is predictive of safety performance. Safety in an organization follows an evolutionary path from the *pathological* through *bureaucratic* to the *generative* level (Westrum, 2004). Westrum tripartite typology was modified by James Reason who introduced the reactive and proactive levels (Reason, 1997) and later used to develop a framework for safety culture research (Parker et al., 2006).

Unlike the development of other safety culture tools (Singer et al., 2007;Sorra et al., 2004), where authors used an industry-based literature review to generate a list of dimensions pertinent to PSC, this tool utilized literature available in primary healthcare. Hence, development of the MaPSaF benefited from the maturity of PSC tools used in healthcare. Qualitative tools require validity testing different from questionnaires, hence the preliminary list was subjected to review and adaptation by five opinions, producing the final list which was used as the conceptual framework for semi-structured interviews with managerial and healthcare staff in primary care. The final tool comprises nine dimensions of PSC (Table 3-1); five levels of safety maturity were developed for each dimension (Table 3-2). The interviewees judged the dimensions to be valid and applicable to primary

healthcare and had little difficulty describing the culture maturity levels except for the generative level which was thought to be unachievable. The tool was subjected to further validation using individual interviews and focus groups conducted among single multi professional groups. Findings from these validation exercises revealed the MaPSaF is a valid tool for evaluating the maturity of safety culture and the discussions appeared to contribute to participants' understanding of safety culture (Kirk et al., 2007). Findings from the initial validation exercises were similar to both the SAQ and PSCHO tools in that perception of safety culture varied according to working team and hierarchy. The unique feature of qualitative tools, unlike quantitative tools which require psychometric analysis to prove their reliability and internal consistency, mean that they can only be analysed using the subjective inferences from study participants. This can introduce a limitation because it is important that the choice of study participants is carefully considered.

Although the tool was initially developed for use in primary healthcare and community pharmacies (Ashcroft et al., 2005), it has been validated for use by the former NPSA (NPSA, 2006) in ambulance, primary care, acute care and mental health settings. The MaPSaf is available in the public domain with a facilitator guide. Although it is purported to be widely used (ESQH, 2008), published research using this tool is limited. Qualitative research can be demanding and presents a number of challenges to the researcher and the participants (Smith, 1998). Using this tool requires the guidance of a well-trained facilitator, the investment of time and resources and the commitment of healthcare staff and may explain its limited use in published research (The Health Foundation, 2011).

3.4.7 The Pharmacy Climate Questionnaire (PSCQ)

A number of tools have been developed to measure safety culture about medication (Fleming et al., 2008;Ashcroft et al., 2009;Colla et al., 2005;Blegen, 2005). One of these tools has been extensively tested, translated into a number of European languages and is available on the public domain for research purposes, is the Pharmacy Safety Climate Questionnaire (PSCQ) (Ashcroft et al., 2009). It is a quantitative tool based on the MaPSaF (Kirk et al., 2007;Parker, 2009) model and Westrum's theory (Westrum, 2004) developed to test safety climate in community pharmacies.

The preliminary tool contained 42 questions on nine themes of safety culture based on the MaPSaF (Table 3-1); commitment to patient safety, communication in the pharmacy,

staffing and management, education and training about safety, team working, incident reporting, investigating incidents and learning following an incident (Table 3-2).

Community pharmacists were recruited by attending a continuous professional development session on risk management. It was administered to 998 community pharmacists in Northern England. Principal component analysis was carried out, resulting in a rejection of seven items and one component. The final tool had 34 items measuring 7 components. The final version displayed an internal consistency, Cronbach alpha of 0.67-0.88.

This tool's distinctive quality in assessing PSC in community pharmacy presents a limitation because it may not be directly transferable to other health settings. However, it has been robustly developed, based on the well-developed theory of culture maturity. It also underwent appropriate psychometric analysis, although using a smaller number of participants than other tools, such as the SAQ, PSCHO and the AHRQ tool.

3.4.8 Gershon Safety Climate Tool

One of the earliest safety climate tools was developed by Gershon et al (2000), based on their colleagues' previous work (DeJoy DM et al., 1995) and supplemented by a literature search and qualitative research. The tool aims to determine whether a hospital's commitment to blood-borne pathogens risk management is related to workers' safe practices. It measures four constructs: demographics, safety climate, self-rated compliance rate and exposure history. The authors surveyed 1240 HCWs with high risk of exposure to blood-borne pathogens from a teaching medical facility in the US and obtained a 60% response rate.

The safety climate construct was factor analysed and six factors were extracted (Table 3-1), and unreliable scale items were rejected. Cronbach alpha coefficients were used as a measure of a factor's internal consistency and retaining items which had a reading of 0.71-0.80.

HCWs perceptions were positive for availability of personal protective clothing but very poor for physical work environment and interpersonal communication. Workers had generally good compliance with following safety practices but 9% reported a recent exposure to blood or bodily fluids. Compliance was three times higher among workers who had a perception of a clean work environment and was positively associated with senior

managerial support and absence of work hindrances. The authors reported that HCWs risk was reduced considerably following the administration of this questionnaire.

Unlike other PSC tools, and similar to those in industry, this tool focuses mainly on worker safety, hence it has limited applications to the wider safety culture issues that may arise in a healthcare setting.

Gershon's Safety Tool was modified by Turnberg and Daniell (2008) to determine the relationship of exposure to respiratory pathogen and safety climate and found to have acceptable psychometric properties (Turnberg et al., 2008).

3.4.9 Japan Patient Climate Scale

Matsubara and colleagues in Japan (2008), realizing that PSC tools developed for use in one country need not be applicable in a different country, particularly when the language and overall culture are fundamentally different, developed a tool tailored for Japanese healthcare staff. The Japan Safety Climate Scale was based on Reason's Error Theory and includes 33 items (Table 3-1) with eight dimensions covering worker safety and organizational climate (see Table 3-1). Items for inclusion in the tool were extracted from the literature and a survey of HCWs who were asked to indicate their areas of safety concerns, followed by expert opinion. The authors distributed the original questionnaire to 1878 HCWs from different disciplines from nine hospitals in Japan and 76.6% returned completed questionnaires, a response rate which was not achieved with other tools. Psychometric analysis was used to retain items that had a Cronbach alpha coefficient and intra-class correlations for test re-test reliability of more than 0.70 and inter-rater reliability of more than 0.60.

The context in which this tool was developed precludes its use in other countries where the language is different.

3.4.10 Summary of Patient Safety Culture Tools

Most PSC tools were developed in the USA except for three; the Patient Safety Assessment tool, Japan Patient Climate Scale and the MaPSaF. In general, questionnaires are easily utilized to monitor PSC changes after interventions, measure PSC in healthcare organizations and compare perceptions of different disciplines and hierarchies of HCWs.

However, they only provide a snapshot of PSC and are best utilised to measure safety climate, which is an aspect of PSC, because they do not give details as to why differences exist. A more accurate assessment of PSC can only be accomplished using qualitative methods such as the MaPSaF. Moreover, in a healthcare institution from a developing country such as RICK, where safety systems are not accessible to all staff, the use of questionnaires will result in incomplete findings. Questionnaires will provide a quantification of patient safety climate attitudes, behaviours and practices but will not offer any explanations as to the beliefs and values held by those workers. Qualitative research methods that employ focus groups and interviews, although costly and time-consuming, would provide a more accurate measure of PSC. The only validated tool for this purpose is the MaPSaF.

Table 3-1 Characteristics of patient safety culture tools

Tool	Safety Dimensions	Theoretical underpinnings	Number of items	Psychometric properties	Advantages	Limitations
SAQ	6	HRO Theory, Donabedian's Model	63	Cronbach alpha: 0.68-0.81	Widely tested, Sound Psychometrics published, Available in the public domain	Poor response rate
AHRQ HSOPSC	19	NR	44	Cronbach alpha: 0.63-0.83	For inter- and intra-hospital comparisons Sound Psychometrics published Available in the public domain	Mainly used in hospitals Poor response rate
PSCHO	9	HRO	45	NR	Mainly used in hospitals	Poor response rate, psychometrics not reported
Safety Climate Survey	10		21	internal consistency (0.86), test re-test reliability (0.92)	Easy to use	Limited use and scale
Safety Climate Scale	NR	NR	10	NR	Easy to use	Limited use and scale
MaPSaF	10	Safety Maturity Model	N/A	N/A	Provides accurate assessment of culture, can be educational	Time consuming, costly and requires expertise
Pharmacy Climate Questionnaire	9	Safety Maturity Model	42	Cronbach alpha: 0.67-0.88	Unique to community pharmacy settings	Limited use in other health settings
Japan Safety Climate Tool	8	Reason's Human Error	20	Cronbach alpha and test- retest reliability >0.70	Tailored for Japan healthcare staff	Limited use with other languages
Gershon Safety Climate Tool	6	NR	20	Cronbach alpha: 0.71-0.80	Measures safety behaviour with safety climate	Limited utility in other settings

Abbreviations: AHRQ HSOPSC = Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture, MaPSaF = Manchester Patient Safety Framework, PSCHO = Patient Safety Culture in Healthcare Organizations Survey; SAQ = Safety Attitudes Questionnaire, HRO= High reliability Organizations, NR= Not reported

Table 3-2Dimensions of Patient Safety Culture Tools

Tool	Dimension
SAQ	Teamwork, Job satisfaction, Perception of management, Safety climate, Working conditions, Stress Recognition
AHRQ HSOPSC	Unit Level: Teamwork within units, Organizational learning, Supervisor/manager expectations and actions promoting safety, Hospital management support for safety, Communication openness, Error feedback and communication, Staffing, Non-punitive response to error Hospital level: Teamwork across units, Hospital handoffs and transitions Safety Outcomes: Overall perceptions of safety, Frequency of event reporting
MaPSaF	Commitment to overall continuous improvement, Priority given to safety, System errors and individual responsibility, recording incidents and best practice, evaluating incidents and best practice, Learning and effecting change, Communication about safety issues Personnel management and safety issues, Staff education and training, Team working
Japan Safety	Continuous improvement, reporting rules/compliance, Patient/Family involvement, Supervisor Safety Leadership, Allied Professional Safety leadership, Patient Safety Committee leadership, Rules equipment availability
PSCHO	The Organization: Seniors management engagement, Organizational resources, Overall emphasis on safety The work Unit: Unit safety norms and unit Recognition, support for safety. Individual: Fear of shame, Fear of blame, Learning
SCSu	NR
SCSc	NR
Pharmacy Climate	Commitment to patient safety, Communication in the pharmacy, Staffing Management, Education and training, Team working Incident Reporting Investigating Incidents Learning following an incident
Gershon Tool	Demonstrable management support for safety problems, Absences of hindrances to work practice, Availability of personal protective and engineering control equipment, Minimal conflict and good communication among staff members, Frequent safety related feedback by supervisors, Cleanliness and orderliness of the work site

Abbreviations: AHRQ HSOPSC = Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture, MaPSaF = Manchester Patient Safety Framework, PSCHO = Patient Safety Culture in Healthcare Organizations Survey; SAQ = Safety Attitudes Questionnaire, SCSc=Safety Climate Scale, SCSu=Safety Climate Survey, NR= Not reported

3.5 Aims and Objectives

The following study aims to describe the safety culture at the Radiation and Isotope Centre Khartoum as perceived by staff working directly with patients i.e. doctors, nurses and pharmacists. The objectives of this study are to:

1. Describe the safety culture at the Radiation and Isotope Centre Khartoum as perceived by staff working with patients.

2. Identify differences in safety culture perceptions according to profession and gender.

3. Explore implications of perception on current practice regarding issues of patient safety.

3.6 Methods

The (MaPSaF), a tool designed for use in a focus group setting, was modified and adapted for this study (Parker, 2009). A focus group is defined as:

> *"a carefully planned discussion designed to obtain perceptions on a defined area of interest in a permissive non-threatening way"* (Krueger 1994, p16)

A key function of a focus group is to gain insight and information from the communication and interactions that occur between participants, who ideally should have similar shared backgrounds and experiences (Kitzinger, 1994). Although focus group findings are not intended to be generalisable, several groups should be run consecutively to avoid the risk of collecting little information if the group participants happen to be detached and not interested in the topic of discussion.

The group interaction and discussion is effective for collecting qualitative, exploratory information and usually generates useful insight into unexplored topics (Kitzinger, 1994). However, the interaction of the group offers several limitations that may include compromising individual confidentiality, potential loss of control over the direction of the group discussion and the risk of dominance of one or more participants (Krueger, 1994). However, these issues can be minimized by improving the skill of the focus group moderator.

Qualitative methods are best suited to this type of study because they yield rich conversational material that can be analysed to understand HCWs' knowledge about safety systems. Qualitative methods have been described as essential in obtaining a thorough description of safety systems in healthcare organizations (Allen et al., 2010;Nieva et al., 2003).

3.6.1 Development and modification of the study tool

The MaPSaF was originally developed for use in several different healthcare settings: acute care, mental health, primary care and ambulance (NPSA, 2006). Although RICK is a tertiary referral centre, it shares certain features with acute care settings in the UK NHS such as: day care, inpatient wards, and outpatient clinics where drugs are prescribed, dispensed and administered in environments with similar pressures. Hence the acute version of the MaPSaf was appropriate for this study (NPSA, 2006).

Although most university graduates in Sudan are bilingual and can communicate well in both languages, the planned research involved HCWs from different disciplines and therefore it was considered appropriate to translate the framework into Arabic. Since the MaPSaF is a validated tool, changes to the language used may compromise its robustness. A translation method, which has been previously employed when other validated healthcare tools have been used where English is not spoken, is back translation (Beran et al., 2006;Jacobsen et al., 2009;Klepstad et al., 2002). Following translation, the tool was subjected to piloting and further modifications to suit Sudanese culture (see Figure 3-1).

3.6.2 Translation of the MaPSaF

Brislin's translation method was modified using an approach published in cross language research (Klepstad et al., 2002), by following three major steps; forward translation, group validation and back translation as explained in chapter 2 and Figure 3-1. The following steps were used:

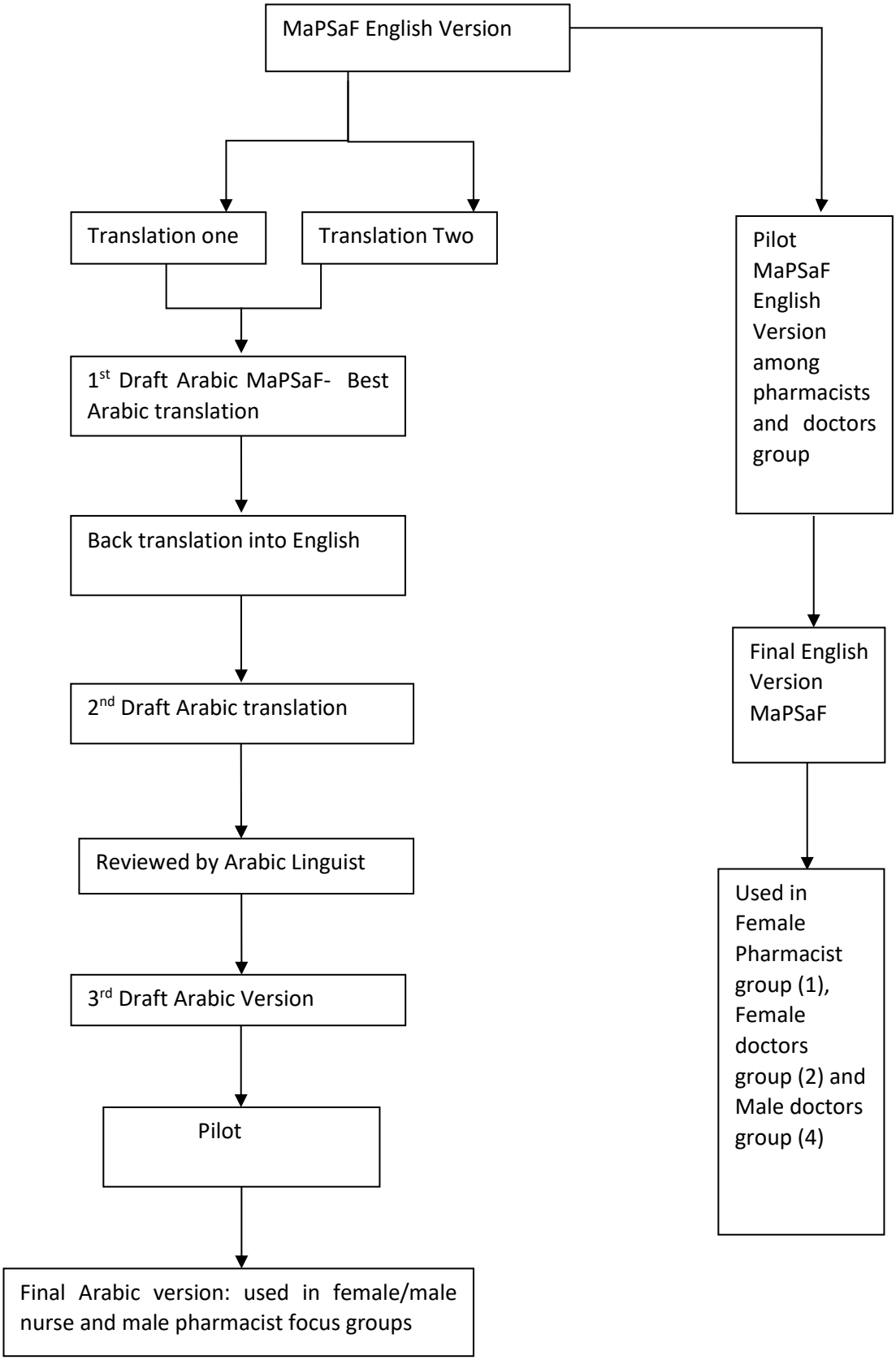


Figure 3-1 Development of the Arabic version of the MaPSaF and the simplified English MaPSaF for use in RICK

1. Forward Translation: In November 2009, three translators separately translated the MaPSaF; these were two members of the research team in addition to a bilingual colleague who worked at a local university. They were asked to use an English/Arabic Dictionary to translate the MaPSaF and formulate Arabic sentences that best described the meaning of the sentences used in the framework.
2. Forward Translation: The translators produced handwritten documents of the MaPSaF translations. The researcher arranged for a series of one hour long meetings with both translators, to discuss and compare each of the ten dimensions of the MaPSaF. During each meeting, the group read through each of the translations, five minutes was given for reflection and each member reported on which of the translations they thought to be most accurate. A discussion followed so that agreement was reached on the final draft translated version.
3. Back Translation: The draft translation was then given to a professional translator who worked at the Linguistics Department at the University of Khartoum. The Linguistics Department is the official translating department endorsed by the government of Sudan. Although other researchers have used a professional translator whose mother tongue is English (Klepstad et al., 2002), it was not possible to have access to such a translator in Sudan. The back translation was discussed in a meeting between the researcher and the translator and changes were made to the Arabic version (Appendix 3-1).

3.6.3 Face Validity of the Arabic MaPSaF

In December 2009, a group consisting of two pharmacists and two nurses, who work as lecturers at the University of Medical Science and Technology (Khartoum), were invited to read and comment on the English and Arabic versions of the MaPSaF. Everyone was given the original English language tool and the translated version, a week before this meeting. The group recommended that the Arabic version to be used with nurses, because most are trained at nursing schools where the teaching is carried out in Arabic. Whereas because both doctors and pharmacists are taught in English when studying for their undergraduate qualifications and hence, the English version would be appropriate for these groups.

The following recommendations were made:

Arabic Version

The participants involved in the validity exercise suggested that some of the Arabic sentences were too academic for nursing staff at RICK. Arabic is a complex language, with many regional colloquial variations, which have been incorporated into the mainstream Arabic that is spoken in Sudan. The group suggested some colloquial terms that were subsequently discussed with the professional translator and a final format was agreed (Appendix 3-2).

English Version

The English version was found to be acceptable but certain terminologies, which were unique to the English culture, were thought to be ambiguous and required further explanation by the researcher, were removed. These were: (Appendix 3-3):

- 'skeletons in the cupboard'
- 'brush under the carpet'

This exercise was also used to test the feasibility of the MaPSaF and 60- 90 minute meetings were considered suitable to conduct the focus groups.

3.6.4 Sample, recruitment and procedures

The focus group interviews were conducted in the main hospital building of the cancer centre. Morgan (1997) recommends conducting three to five focus groups, depending on the nature of the study and the people involved. Since this study was of an exploratory nature, aiming to understand Patient Safety Culture among staff in direct contact with patients, it was decided that discussions should be carried out with HCWs involved in the prescribing, dispensing and administration of chemotherapy.

These were the nurses, doctors and pharmacists, with separate groups for each gender. Such homogeneity would allow participants to provide rich material during the discussions because, being of common backgrounds, they would have shared experiences and be less inhibited (Krueger, 1994). It was envisaged at this preliminary stage of the research, where the healthcare team dynamics were not fully understood, specifically and in societies who have a high masculinity index where males can dominate or even limit the scope of the conversation (Hofstede et al., 1991), that single gender groups would be justified. Separate

gender groups may be conducted when discussions are expected to probe sensitive matters (Morgan, 1997). Given the toxicity profile of chemotherapy (Hemminki et al., 1985;Selevan et al., 1985;Barton et al., 2013;Dranitsaris et al., 2005), it was anticipated that discussions regarding reproductive safety during the manipulation of these agents would arise. Hence, as a precautionary measure and to ensure that focus group participants experienced little inhibitions during discussions, groups were conducted with single genders.

Purposive sampling, a standard technique followed in focus groups, was used (Morgan, 1997), because generalisability was not a desired outcome of this study (Barbour et al., 1998;Huston et al., 2008;Krueger, 1994;Morgan, 1997). To ensure that participants had maximal experience in using chemotherapy and would be able to recall their experiences, HCWs with at least two years' experience in the cancer centre, were approached. There is little consensus about the optimal size for a focus group, with some experts advocating group sizes ranging from 6-8 (Krueger, 1994) to 8-12 individuals (Barbour et al., 1998), but the number of participants may be as few as 3 (Barbour et al., 1998) to 4 (Krueger, 1994). A minimum number of four participants in each group was chosen because these participants could be accommodated in the restricted space available and the time constraints placed on staff at the cancer centre.

It was aimed to recruit participants from each department who had different responsibilities to ensure diversity of experience, but to ensure that they are of similar grade to allow uninhibited discussions.

After discussion with the research supervisors, it was agreed that verbal consent would be appropriate at this early stage of the research, following the process outlined in Chapter 2. Each group of HCWs were given a PIL (Appendices 3-4 and 3-6) and consent form (Appendices 3-5 and 3-7). to read and sign upon agreement as outlined in chapter 2.

<u>Pharmacists' Focus Group</u>

At the time of this study, RICK pharmacy employed a total of 17 pharmacists, 12 working in the three dispensaries, 3 clinical pharmacists and 2 pharmacists who worked in a managerial position. The three dispensaries were:

- Outpatient dispensary
- Inpatient dispensary
- Community pharmacy

The clinical pharmacists worked in rotations and participated in consultant-led ward rounds, clinical meetings as well as medical and nursing staff education. Clinical pharmacists supervised nursing staff at the chemotherapy administration unit as well as running the medicine information centre. A total of 15 pharmacists were eligible to take part in this study. The female pharmacists focus group was the first to be held on the 1st March 2010 and was conducted in the Medicines Information Centre. Male pharmacists chose the community pharmacy office for their focus group, which was conducted on 19th August 2010.

Nurses Focus Group

During 2010, when this project was carried out, the wards were run by two matrons and 26 nurses, who worked in shifts between the various wards. A total of 26 nurses were eligible to participate in the study because the study targeted nurses at the forefront of patient care rather than managerial level. Two separate gender groups were recruited; four female nurses and four male nurses. It became clear, after the first focus group, that conducting sessions with a larger number of participants was not possible, because of the nurses' work schedules; groups of 4 were considered to be a reasonable focus group size in this setting. The female nurses focus group was conducted on 8th March 2010, at the nurses' office, situated on the inpatient wards. The male nurses focus group was conducted on 16th August 2010, in the palliative care nursing office. It is worthwhile to note that no major changes had taken place during the intervening time which would invalidate the findings from this focus group.

Doctors Focus Groups

At the time of conducting this research five consultant units were running clinics at RICK. Each senior consultant had a team that consisted of 1-4 consultants, 1-4 registrars and 2 junior doctors, according to the patient load. All the doctors, with the exception of the junior doctors, were involved in assessing out-patients and prescribing chemotherapy. It was intended to run two gender based groups represented by a range of staff: registrars (n=6), junior consultants (n=4) and recently qualified consultants (n=3). The acute consultants had been qualified for one year whereas the junior consultants had been qualified for over three years but remained part of another consultant's team. To obtain participants with a variety of backgrounds, two senior consultants and two junior consultants were approached to participate in the female group, which was conducted on 15th March in the female doctors' mess. It was only possible to recruit male doctors for their focus group interview on 19th

August. The focus group was conducted in the male doctors' mess. This group consisted of registrars only because they weren't included in the female doctors group and it was thought that they would give valuable insight into training and practice.

3.6.5 Focus Group protocol

The NPSA published an online guide for facilitators using the MaPSaF, to direct the focus group research in healthcare (NPSA, 2006).

Participants were asked to choose a location that was suitably furnished to allow participants to see each other's faces and where interruptions would not occur. All participants agreed that a lunchtime meeting would be most appropriate where refreshments were provided. Participants were given the choice of using either the English or Arabic version of the MaPSaF.

3.6.6 Moderators

Kidd and Parshall (2000) recommend at least two members of the research team are present during focus group discussions, including preferably the principal researcher, to ensure that verbal and non-verbal exchanges are recorded in a robust manner. A moderator and assistant moderator were present in all the focus groups, each with different responsibilities (Table 3-3). The principal researcher moderated the discussion, while an academic colleague, who had been involved in initial meetings to validate the tool, acted as the assistant moderator. The main role of the moderator was to steer the discussion towards the aims of the interview and maintain the interest of the group. Whereas the assistant moderator organized the seating plan, recorded the discussion using a tape recorder, as well as being responsible for other activities that would otherwise distract the moderator.

Table 3-3 Tasks assigned to focus group moderators

Moderator	Assistant moderator
• Welcoming the group • Presenting information about the purposes of the interview. • Explaining the role of each member of the group. • Assisting participants in understanding the elements of the MaPSaF • Facilitating the discussion • Taking notes during the focus group	• Distribute the food and refreshments • Draw a seating plan for all participants of the focus group • Distribute and collect the required paperwork • Monitor time and tape recorder

The focus group sessions were conducted in the following manner:

1. The moderator thanked the participants for agreeing to be involved in the focus group.

2. The moderator presented a ten-minute introduction to the MaPSaF and an overview of the session, including what was expected of the participants (Appendix 3-8).

3. Permission to tape record the conversations was obtained from all the participants.

4. The MaPSaF was distributed amongst the participants.

5. The group was given 20 minutes to read the MaPSaF sheets and asked to circle on the evaluation sheet the level which best described their team and the one which corresponded with the organization (Appendix 3-9 for the English evaluation form and Appendix 3-10 for the Arabic evaluation form).

6. Each member of the group was subsequently asked to confer with the person sitting closest to them to allow the participants to compare their evaluations and record the reasons why they chose them.

7. The last step involved engaging the group in discussions around the choices they had made. The notes written down by each pair were collected and both

evaluations and notes were written on a flip chart and participants were asked to discuss the reasons for their choices.

3.6.7 Data management and analysis

After obtaining consent from focus group participants, a tape recorder was used to record each of the sessions. Both audio-taping and *verbatim* transcribing are considered standard practice when documenting discussions during focus group interviews (Krueger, 1994). However, audio recording is more accurate and convenient because it allows further verification of conversations by repeated listening and doesn't distract the moderator from steering the interview.

The moderator and assistant moderator met after each focus group, to discuss participant notes, moderator notes and tape recordings, and label them appropriately. Initially the recorded data were listened to repeatedly by the principal researcher and transcribed *verbatim* in the Arabic language. The recordings were given to a second member of the research team to validate the accuracy of the transcriptions. The Arabic transcript was translated into English language for purposes of analysis using the methodology outlined in chapter 2.

The English transcripts were studied in detail by the principal researcher and key themes and categories were identified using the directed approach for content analysis.

Transcribed interviews were entered into NVIVO; a qualitative analysis software system for storage and coding. Frame work Analysis, as described by Richie and Spencer (1980), was used for analysis of the results. Richie and Spencer (Richie et al., 2003) describe this method as:

> "*Thematic framework is used to classify and organize data according to key themes, concepts and emergent categories. As such each study has a distinct thematic framework comprising a series of main themes subdivided by a succession of related subtopics. These evolve and are refined through familiarization with the raw data and cross-sectional labeling. Once it is judged to be comprehensive, each main theme is displayed or charted in its own matrix where every respondent is allowed a row and each column denotes a separate sub-topic" (Richie, 2003 p 220)*

Framework analysis has been extensively used in patient safety research (Duncan et al., 2012;Schwappach et al., 2010;Schwappach et al., 2012;Williams et al., 2013;Watson et al.,

2006;Lesar et al., 2007;Taxis et al., 2003a;Ashcroft et al., 2005). It is an analytical method which is suited to the analysis of qualitative data that covers similar topics and themes and provides a method for achieving a holistic description of the data. However, its major drawback is its limitation in the analysis of heterogeneous data.

Findings from the safety culture maturity scoring exercise were reported using MaPSaF dimensions. However, and in view of the findings of this research (Section 3.7), and after discussion with the PhD supervisors, it was decided that it would not be conducive to map themes emerging from the focus group discussion to the MaPSaF. Instead, these were mapped to Reason's (1997) components of an "informed culture" as detailed in Table 3-4. Such a culture exists when leadership and staff report errors (a reporting culture), where leadership understands when a safety incident is intentional or non-intentional (just culture) and where those errors are used constructively in future learning activities. An important dimension to a safety culture is seen as the ability for hierarchies to flatten in times of need, where the expertise of individuals is sought by leadership.

Table 3-4 Themes of safety culture (Reason 1997 p 195-196)

General Theme	Definition
Reporting	An organizational culture in which people are prepared to report errors and near misses.
Just	An environment of trust where people are actively encouraged to report their safety concerns without fear of scapegoating or retribution, whilst at the same time recognising the difference between intentional and unintentional safe acts.
Flexible	A climate that adapts to changing demands and involves a shift in hierarchies that allows control to pass to experts at the frontline.
Learning	An environment that supports feedback to all staff as a result of error investigations and feeds results into a national reporting mechanism.
Informed culture	The overarching safe culture where those who manage and operate the system have current knowledge about the human, technical, organizational and environmental factors that determine the safety of the system as a whole.

3.7 Results

A total of six focus groups were conducted with 4 participants in each. Hence there were 24 HCWs included in the study (Table 3-5).

The pharmacist focus group was conducted as planned but the plan for the nurses and doctors' groups had to undergo modifications to accommodate nurse work schedule, doctors' examinations and other issues. When conducting the female doctors group, the registrars were sitting their examinations, and they indicated that they would not have time to participate in a focus group. Therefore, it was only possible to conduct a discussion group with consultants. Since the female doctors group was only composed of consultants, it was decided to recruit only registrars to the male doctors group. Table 3-5 provides details of the composition of these groups.

Table 3-5 Composition of focus groups

Focus Groups	**Composition of groups**	
	Female	**Male**
Pharmacists	1 dispensary pharmacist, 2 clinical pharmacists and 1 department supervisor	1 outpatient dispensary pharmacist, 2 inpatient pharmacists and 1 department supervisor
Doctors	2 senior consultants,2 acute consultants	2 senior registrars and 2 junior registrars
Nurses	1 chemotherapy day nurse and 3 ward nurses	1 chemotherapy day nurse, 2 ward nurses, 1 specialist nurse

Results of MaPSaF Scoring

The three focus groups rated the ten dimensions of the MaPSaF mostly, at the lowest level of maturity -reactive and pathological (Table 3-6). The pharmacists' group rated their own at different levels of maturity to the organization, rating the latter at a lower level to their own team. For example, pharmacists rated the team's priority to safety as reactive whilst that of the organization as pathological. Both doctors and nurses rated both their own

teams and the organization at the same level of maturity at each of the ten MaPSaF dimensions, hence table 3-6 shows one column for both team and organization. Although none of the groups rated the dimensions at the higher maturity levels (bureaucratic, pro-active and generative), it is noteworthy that nurses rated all ten dimensions as pathological.

Results of the Focus groups

Focus group discussions were mapped according to Reason's dimensions of safety culture and further analysed to reveal components of these general themes, as listed in table 3-7.

When analysing the quotes, several situations were described in which HCWs perceived they felt encouraged to report an error, which were subdivided as components of a *"reporting"* culture. Error reporting was not according to organizational systems but occurred in several situations due to individual initiatives, when there was involvement of external bodies, when they were assured of confidentiality and when they felt they were required to resolve a problem with a specific patient. Other situations which discouraged HCWs from reporting were lack of knowledge about reporting systems, near misses, failure to recognise errors, confrontations and blame, which was illustrated with examples of disrepute and punishment. During the conversations, accounts of some errors were mentioned.

Conversations mapped to a *"Flexible"* culture identified themes that were key issues contributing to shifts in hierarchies such as team-working and communication.

During focus group discussions, instances where participants learned from errors were mapped as subthemes of a *"learning"* culture. None of the participants were able to recall incidents where they had learned from errors in a systematic manner; however, on an individual basis, participants observed the situations where their colleagues were involved in an error and used wisdom to avoid falling into similar traps.

Much discussion involved the human factors that can lead to errors and these were mapped as components of an *"informed"* culture. Issues that were discussed focused on the role of leadership in the organization; human, technical, organizational and environmental sub-themes were identified.

Table 3-6 Safety culture scoring among focus groups using the MaPSaF

MaPSaF Dimension	Focus Groups			
	Pharmacists		Doctors*	Nurses*
	Team	Organization		
Commitment to overall continuous improvement	R	R	R	P
Priority given to safety	R	P	R	P
System errors and individual responsibility	R	R	P	P
Recording incidents and best practice	P	P	P	P
Evaluating incidents and best practice	P	P	P	P
Learning and effecting change	R	P	P	P
Communication about safety incidents	R	P	P	P
Personnel management and safety issues	R	P	R	P
Staff education and training	R	R	R	P
Team working	R	P	R	P

Doctor and nurse focus groups rated both the team and the organization at the same level
Abbreviations: P: Pathological; R: Reactive.

Table 3-7 Themes emerging from focus group discussions

General Theme	Components	Examples
Reporting	Ease of reporting	Enablers: External body involvement, resolution of problem, individual initiatives Disablers: Knowledge of reporting systems, near misses, recognition of errors
	Confidentiality	Confidential, confrontational
	Response to reported incidents	Punishment, reputation, errors are ignored
Just	Actions	Intentions, work systems, violation
	Consequences	Patient harm, risk of errors
Flexible	Team working	Hierarchy, trust, job descriptions
	Communication	Top-down, lack of communication
Learning	Experience	Informal observations
Informed	Leadership	Human- employee wellbeing, self-esteem, Organizational- job descriptions, procedures Environment- Busy work environment, disorganization Resources- equipment, training

3.7.1 Reporting

The themes related to reported, emerging from focus group discussions were categorised into three further components, ease of reporting, confidentiality and response to reported incidents.

3.7.1.1 Ease of reporting

Focus group participants discussed factors that they perceived enablers to reporting incidents or factors that prevented HCWs from reporting errors. The latter were categorised as disablers of reporting.

Enablers

Involvement of external bodies

Focus group participants explained that some hospital departments had good reporting systems because they were audited by an international agency such as the International Atomic Agency (IAA). Group discussions explained that the hospital management would only recognise errors when there was a risk that the Ministry of health would be involved. Such error reporting enabling aspects were only mentioned by doctors and pharmacists and not by any of the nurses. For example

> *"They (Physics department) have that international association, yeah the IAA, to assist them and make sure that their procedures are up to date. If it wasn't for that .... what do you call it? that IAA, they wouldn't be so complete"* **(Consultant A Focus Group 3)**

> *"…… if news has reached the Ministry of Health, the whole hospital starts to do something. There are other things that would start the development of work processes, such as: when an important patient is involved or a minister comes with a co-patient or a patient……This is how we do our work here, so it's like we need a clip around the ears to do anything."* **(Pharmacist C Focus Group 5)**

Resolution of problems

Both female and male nurses in particular expressed the view that in the event of an error occurring, in order to reduce harm and save the patient from complications, they may report their error to others who they saw as allies and being more knowledgeable than themselves. The purpose of reporting in this example was to resolve problems and thus the approach used would be informal and on a personal basis. Examples from the nurses are:

"If I make a mistake, I just go to pharmacy and nobody needs to know about it" **(Nurse D Focus Group 2)**

"No one is immune to making mistakes but why would you contact management about that. You need to know what the error is and how to handle the error and how to save the patient from the complications. That's all." **(Nurse A Focus Group 6)**

"so, I went and found out what to do and how to fix it because I don't want to harm the patient, and in such an instance, I mostly know how to have a quick fix. I have my own fixes, yes, I do. I know when I need to contact the consultant or contact the pharmacy." **(Nurse B Focus Group 6)**

Individual initiatives

Although all HCWs explained that they have no knowledge about incident reporting systems, two focus group participants described that they have sometimes felt it was necessary to report a safety incident in a formal manner. In the two situations described below, the HCWs felt that their colleagues dealt with the matter with mistrust, manifested by surprised looks and aggressive behaviour. None of the nurses were able to give examples of when they were involved in any sort of formal error reporting.

"When I was a new doctor at RICK, there was a medical error on the ward. I enquired if there was an incident reporting form and all I got were looks of surprise. So, I wrote a letter to the nurse in charge and the Chief Executive (CE) of the hospital and copied in his deputy detailing the incident…." **(Registrar B Focus Group 4)**

In another situation, a patient returned a vial of cytotoxic medicine and told the pharmacist that there was something wrong with the vial.

".....I said to the patient that the nurse needs to report this to the senior nurse. That they should write to me an official letter saying that this injection was faulty before they opened it. Would you believe it, the nurse came (a few minutes later) into the pharmacy and tried to strangle me, shouting we aren't thieves man, we aren't this and we aren't that" **(Pharmacist 3 Focus Group 5)**

Disablers

Knowledge of reporting systems

A lack of knowledge regarding hospital incident reporting systems emerged from focus group discussions among all the healthcare teams. However, female nurses assumed that these systems must be in place but attributed their ignorance to poor communication by senior management. For example:

> "*Policies? There aren't any. Or am I mistaken (directing this to other participants in the group)?"* **(Nurse C Focus Group 2)**
>
> "*They (management) must have discussed them (the safety policies) in their meetings. We know that they have regular meetings upstairs in the office but no one tells us anything, we don't even know what these meetings are about…."* **(Nurse B Focus Group 2)**
>
> "*…. I don't personally know who to inform when an error occurs"* **(Registrar A Focus Group 4)**

Near misses

Another obstacle to error reporting was near misses. A male doctor explained that if the error was recognized early enough and corrected, it would be more constructive to deal with it at a personal level rather than involving management, as explained below:

> *"We had an incident last week when a nurse weighed the patient incorrectly. He recorded a weight of 95kg but the patient looked too thin to weigh that much, so I asked the nurse to re-weigh the patient and there was a 30kg difference. The patient was receiving intensive chemotherapy with high doses and such an error could have been very dangerous. Instead of reporting this anywhere, I took the nurse aside and talked to him saying things like "you should be more careful" and "I know that you used to be reliable."* **(Registrar B Focus Group 4)**

Recognition of errors

Although formal error reporting systems were not recognized, some HCWs did report errors using verbal and written methods. However, several reasons for poor reporting were proposed. Nurses suggested that some individuals may not be aware that they had committed an error and therefore would not see the need to report their actions, whilst doctors attributed poor error reporting to incomplete patient notes, which would make it

impossible in some situations to identify whether an error had occurred. Below are examples from the nurses' and doctors' discussions.

> *"But does everybody know that they have made an error, some may not even know that they have made an error? That's happened to me before, yes me the same person sitting in front of you. I didn't know I had made an error but one of the other nurses pointed it out to me"* **(Nurse B Focus Group 6)**

> *"The basics of safety are missing, the patients' notes are incomplete most of the time and hence if a problem arises, no one knows what the cause is. We need systems to ensure safety and to be able to identify safety issues."* **(Registrar B Focus Group 4)**

3.7.1.2 Confidentiality

Both nurses and doctors felt that confrontation in front of other HCWs and patients was damaging. Doctors implied that confidentiality was important and conducive to reporting of errors. For Example:

> *"… Pharmacist (X) was very aggressive. If any of us were involved in an error (X) would come into the clinic with the prescription in her hand and start shouting. No one likes being shouted out in front of others and not in a general clinic."* **(Consultant A Focus Group 3)**

A nurse explained that other nurses may feel resentful if they are corrected in front of other staff and patients. Below is an example.

> *"Not everyone listens, some people may resent being told how to do their job. Not all people are the same and it also depends on the way they are being told. So, if you call me into the office and speak to me nicely, that would be different from when you shout at me in the ward."* **(Nurse B Focus Group 6)**

3.7.1.3 Response to reported incidents

Errors were handled in a number of different ways both by the hospital management, by staff and sometimes the patient. It was implied that although most error reports were ignored by senior management, sometimes individuals involved in error may be subjected to punishment.

Punishment

All focus group participants revealed that they felt uneasy when they had been involved in reporting an error, they indicated they were met with unfair treatment. Punishments were either in the form of disciplinary action or verbal reprimands.

> *"If I made a mistake, then the matron will investigate this and will start disciplinary action against me"* **(Nurse B Focus Group 2)**

> *"… when we were in chemotherapy, one of the students made the mistake of mixing cisplatin with adriamycin in one bag. I recognised there was a problem, when I saw the amount of drug in the infusion bottle and there was also some medicine spilt on the floor. I contacted the pharmacy straight away and showed them what happened. The pharmacy said we should get the nurse to pay for the medicine."* **(Nurse B Focus Group 6)**

Some participants proposed that punitive action is an effective approach to error prevention. Below is an illustration of this:

> *"They (nurses) don't understand instructions. They would ignore the written instructions to give the patient hydration……. If the administration has a working punishment system so when people work they would know they are held accountable for what they do, only then we would have safe systems"* **(Pharmacist B Focus Group 1)**

However, nurses particularly expressed that a better approach to error prevention would be to provide support to staff who admit to their own error, as explained below:

> *"there is a difference if the error was reported by the co-patient or by the patient than when the nurse goes to the management and reported their own errors. If the nurse reports their own error, I would think the management would stand by him and support him and solve the problem and in the end, there is a solution to every problem."* **(Nurse B Focus Group 2)**

Reputation

Male doctors and nurses on more than one occasion expressed concern that reporting of errors was avoided because HCWs felt that it may affect their reputation. These opinions were not shared by other groups but appeared to identify several aspects; the reputation of colleagues, the reputation of the whole organization and personal and individual reputation.

A male nurse explained that it was important to avoid bringing shame and disrepute to fellow HCWs when an error occurs, because errors can be managed without exposing those who are involved. An example quote is detailed below.

> *"I can't say to a patient that the pharmacist has given them the wrong medicines, Isn't that, right? I will take the medicine myself back to the pharmacy. That's what we do. I take the medicine back to the pharmacy and tell them what the problem is. ……never show the patient what had happened, otherwise they would lose faith in the medicines. We just take the medicine very quietly to the pharmacy and never say anything that would reflect a bad picture of our colleagues, because this is the reputation of the hospital and in the end, this pharmacist is our colleague."* **(Nurse B Focus Group 6)**

A male doctor described how, when an error was reported, this may affect his future as a medical practitioner. This was because this information could be communicated to others and the one bad incident might therefore tarnish the doctor's reputation in the future.

> *"We also work and live in a small circle and when word gets around that a certain doctor was involved in an error, people will never forget."* (**Registrar A Focus Group 4)**

Another reason for purposefully concealing an error was reported to be personal ego as illustrated in the quote below from male nurse.

> *"But there are people who keep quiet about it. They are big-headed and can't take instructions from any one……, so they just keep quiet"* **(Nurse B Focus Group 6)**

<u>Errors are ignored</u>

All groups of HCWs described experiences where management ignored the informal methods of error reporting, practiced at the centre. Below are two typical opinions from a female pharmacist and a male doctor.

> *"….. the deputy manager may look concerned but he won't do anything about it"* **(Pharmacist C Focus Group 1)**

> *"I don't think that anyone in this hospital would take an error seriously……."* **(Registrar A Focus Group 4)**

A male doctor wrote a number of incident reports but felt that management disregarded his efforts and consequently he stopped reporting errors. He explained:

> *"I didn't receive a response to my letter. I continued to write reports of incidents for a whole year afterwards but eventually stopped when all were ignored……. So now I will just sort out the problem myself and not get anyone from management involved. I don't care anymore."* **(Registrar B Focus Group 4)**

Nurses perceived that there were simple technical reasons why errors were ignored by management, whereas most doctors perceived the reasons for concealing errors were not necessarily innocent. Nurses indicated that the busy and disorganized work environments were the main reasons that prevented management from investigating an error properly. For example:

> *"There is never any follow up to errors in chemotherapy. How would you follow up anything? The wards are not organized. The number of patients is too high and the number of staff hardly covers them."* **(Nurse B Focus Group 6)**

But doctors felt that management ignored errors as part of a well-conceived plan to cover up because they were also responsible and ultimately accountable for those errors. This is explained in a number of quotes below:

> *"When I used to raise, the issues surrounding an error, I found that it used to stop at the chief nurse, the medical manager or the human resources manager. I discovered lately that senior members of staff are involved in similar errors."* **(Registrar B Focus Group 4)**

> *"People cover up for each other because they know that they have either been previously involved in the error themselves or will be involved in an error in the future."* **(Registrar C Focus Group 4)**

In one incident, an inquiry was set up by the Ministry of Health to investigate the causes of machine breakdowns at the hospital. According to the accounts from male doctors, the investigation took nearly three months and involved personnel from National Security. However, none of the HCWs were aware of the final findings from the investigation. Below are illustrative quotes.

> *"…. the radiotherapy problem was raised to the Minister of Health and then onto the presidency office and as a result, an investigation team was sent to the hospital.*

The investigation team was from National Security and they decided to come and spend three months in the hospital dressed as normal patients or co-patients." **(Registrar B Focus Group 4)**

"We haven't heard anything from that "report", we think it was stopped at the presidency office because the names mentioned are in close alliance with the governing party" **(Registrar C Focus Group 4)**

3.7.2 Just culture

Themes from focus group discussion were mapped to requirements of a just culture. The intentions of the HCW in provision of care were discussed. Focus group participants discussed the requirements they needed for appropriate actions (good patient care) and provided examples of when known work practices are violated. Some examples of consequences of errors were described by participants

3.7.2.1 Intentions

Discussions from focus groups revealed that, although the intentions of most HCWs were to provide the best care to patients. Examples from these focus groups were:

"We are concerned with patient safety first of all, for all nurses the patient safety issue is very important to us all because we are always with the patient. We are very concerned here, the patient who comes to us is not well to start off with and it's our responsibility to make sure that they are safe and receiving the best type of care. We have to ensure everything is in order …" **(Nurse A Focus Group 6)**

"Patient safety is very important to us because we double check the prescription, we make sure to place an administration sheet (in the patient's clinical notes)" **(Pharmacist B Focus Group 1)**

"…… but our aim is to provide patient care and to receive training" **(Registrar B Focus Group 4)**

3.7.2.2 Actions

<u>Work systems</u>

Focus group participants explained that some elements were essential for good patient care: training, the work environment, tools, equipment, quality health systems, procedures

and policies. However, the discussions revealed that for much of the time these elements were either disorganized, inadequate or both.

> "*They (senior doctors) tell us what to do and how to do. I don't know of a job description; I mean we don't have one."* **(Registrar B Focus Group 3)**
>
> *"We in the private wing don't have a wash basin, how can we talk about safety and about quality, How? If nurses don't have access to a wash basin to wash their hands. I have to wash my hands in the toilet, and that's where I wash for my prayers and wash my hands in the toilet before I can eat my breakfast and before I can deal with a patient. You know? Why? Where does quality start? I would like to know?"* **(Nurse B Focus Group 6)**
>
> *"They brought that (pointing to the cytotoxic waste box) in some time ago and once that is full they should come and replace it,……. It's overflowing now, I suppose, one of them should come on a weekly basis to check the boxes and replace them if need be*." **(Nurse C Focus Group 6)**
>
> "*We have not had a simulator in the radiotherapy department for more than a year, which is very dangerous for patients. Patients who need radiotherapy treatment must have their sessions planned under a simulator to make sure that the vital organs are protected. Because we don't have a simulator, we end up carrying out the planning manually and patients suffer from damage that is easily avoidable*" **(Registrar C Focus Group 4)**

<u>Violations</u>

All focus groups had concerns about violations of work systems which they thought contributed to poor overall quality and errors. Examples of these violations were taking *"short cuts"* and poor documentation

Discussions revealed that some nurses use *"short cuts"* without understanding the consequences of their actions. They would intentionally ignore written instructions leading to patients missing essential treatment.

> *If they see a patient with more iv fluids than drugs, they will give the easiest and only give the drugs and the patient may miss out on the iv fluids. That could be dangerous, but they don't know because no one told them of the importance of*

giving iv fluids to a patient on 'chemo'. They don't even understand the effect of these fluids on the patient's health…." **(Nurse B Focus Group 6)**

3.7.2.3 Consequences

Neither participants in the pharmacist nor nurse focus groups could give examples of situations when patients were harmed or were exposed to risk of errors. However, some of these cases were described by female doctors and male doctors. The section below presents some examples of harmful consequences that transpired from unsafe acts

Patient Harm

In one instance a patient was harmed because the consultant wrote the same prescription for a patient, two weeks in a row. This chemotherapy should be given at three weekly intervals and the doctor did not realize that the dose was not due. The patient received the medicine and suffered serious side effects.

"…one of the senior consultants wrote the drug for the patient two weeks in a row. This patient came in with severe side effects and was very unwell. The consultant asked her how she got the drugs and when she told him it was "you" (meaning the consultant, the doctor pointed with her finger at the air enacting the patient's action) ……" **(Consultant A Focus Group 3)**

Risk of errors

Both female and male doctors thought that errors and missing data in the hospital's patient medical records contributed to compromising patient care. The absence of appropriate documentation in patient medical records meant that errors may be missed and that information is mostly incomplete. Doctors in this situation expressed their frustration because they had to obtain essential medical information from patients who may be in a critical condition and hence unable to provide a comprehensive history. An example is given below

"…. I was called to see a patient last week, but I looked through the file to discover that he is not in my team and that there are no records of why he was admitted. I was able to find out this information from the patient and not from the file. I think that this is unacceptable and everyone is exhausted from the lack of proper systems of work" **(Registrar A Focus Group 4)**

3.7.3 Flexible culture

All groups perceived that teamwork was ineffective within the hospital because of the lack of team dynamics, job descriptions and ineffective communication.

Team work

Participants provided insight into the nature of teamwork at the cancer centre. Nurses perceived that teamwork did not exist within the hospital or within the nursing teams themselves. However, there were isolated situations where teamwork was evident but this was dependent on the individuals involved rather than work systems. Below are typical quotes:

> *"……. nurses don't work together here. Everyone does their own thing and no one asks you unless there is a problem."* **(Nurse C Focus Group 2)**

> "*This depends on how people act and their personalities, because this is the type of job that needs more than one person's input"* **(Nurse A Focus Group 6)**

Conversations revealed that the precise role of each individual in the team was felt to be ill-defined. A typical quote from male pharmacists' discussions is detailed below.

> *"…team work to me is just like a football game, with everyone knowing their precise role. They should all work together to achieve the objective, but here our roles are not precise and not known. We would like to help each other; we would like to cooperate but not many know what their precise role is in achieving the desired objective……I still feel a bit lost in the pharmacy not knowing which jobs of the pharmacy have been allocated to who? Who would be responsible for certain tasks? We have started distributing tasks and responsibilities but I still can't see a clear picture. I think it would take time"* **(Pharmacist B Focus Group 5)**

Team hierarchies were described as rigid without flexibility, where the interventions of juniors were ignored and the orders from senior doctors are implemented. One particularly unsafe situation was described by a male doctor, where a senior consultant intentionally wrote a prescription for a highly toxic drug to treat a non-chemo sensitive disease, but refused to listen to an intervention from the junior doctor:

> *""You think that we should be respected as doctors but the senior consultants don't count us as members of a team. …… he (senior consultant) insisted on giving the patient a drug that is very toxic and not effective. When I suggested to him to change*

> *the therapy, he had a go at me and said the patient was his and that he could easily put a knife to his throat and no one can argue with him about that."* **(Registrar C Focus Group 4)**

All healthcare teams revealed that they lacked trust in each other. However, there were specific trust issues with respect to nursing staff, where examples of suspicions of bribery and inappropriate behaviour were described in the discussions. Typical quotes from male pharmacists' and male nurses' discussions are described below.

> *"Some departments are ready to co-operate. If you want to help bring the medicines from the pharmacy to a patient on the ward, they think you are receiving money 'under the table'. You know, there are a few..... a few especially in the pharmacy. I mean there are people who reflect a bad picture of their colleagues"* **(Nurse B Focus Group 6)**

> *"Yeah, Dr X once said it to me in front of Dr Y. It was actually a patient of Dr Y's that he had phoned to tell me about and see what I could do to help her. I helped her with her paperwork and when Dr X saw me he said: (Oh you are always chaperoning a pretty girl). I got very angry with him, I said to him I am free to do whatever I want, be a co-patient, or anything, I am free to do as I want…"* **(Nurse B Focus Group 6)**

3.7.3.1 Communication

Breakdowns in communication between HCWs had the potential to lead to tense work relationships, arguments and errors. Two male doctors described how the hierarchical communication led to a confrontation with management.

> *"We came one morning and discovered a letter posted on the door of the doctors' mess with a timetable for our working hours. We convened in the office and decided unanimously to boycott the 'on call' shift and not work even if they paid us one thousand pounds a night. We all felt they had no respect for us. We are registrars and pending consultants. This issue was mismanaged in a shameful way because when we went to the deputy chief he chucked us out of the office."* **(Registrar C Focus Group 4)**

Focus group participants explained how hierarchical communication made them suspicious of management and led to loss of trust. This manner of communication was considered by male nurses to be a deterrent to discussing issues with management. In contrast, the female nurses thought this acceptable in a management relationship. Below are typical quotes.

"*…. It should start at the bottom, that's why what they do is mainly superficial and no one really takes notice. These people, they are sitting at the top and start at the top. They come passing through, but we keep our mouths shut and we don't speak to them"* **(Nurse B Focus Group 6)**

"The head nurse and the matron are responsible for us and they should tell us what goes on in these meetings and what they are about" **(Nurse D Focus Group 2)**

Failure in communication related to tasks and processes was common in the cancer centre and HCWs explained how this can sometimes lead to errors. A pharmacist described a situation where there was a failure of communication with respect to changes in opioid recording procedures. He felt that this could have led to an error as described below:

"I once came in and started dispensing morphine on a weekend and didn't realise that they (dispensary staff) have changed the morphine dispensing procedure. Obviously, I recorded things wrongly and didn't discover my mistake till two months later. I wasn't with the staff the day before and hence missed out on this information and the change in procedure. I don't know what you would call this, random processes, no system, I don't know. …" **(Pharmacist C Focus Group 5)**

3.7.4 Learning culture

All healthcare teams described concealing errors and therefore as a consequence the team lost the opportunity to learn from such errors in a systematic manner.

Informal observations

Nurses and doctors in particular revealed that they observe the consequences of errors committed by colleagues and use them as a learning experience. However sometimes this method was ineffective as in the examples below.

"If a problem happens, then I would know what to do next time. ……., but before that we learnt from experience" **(Nurse B Focus Group 2)**

"The team usually comes together to try and solve the problem and this is usually done on a personal level according to each doctor's ideas or relationships with other departments. But I can't guarantee that everyone would remember not to do that same error again" **(Registrar B Focus Group 4)**

3.7.5 Informed Culture

System inadequacies mentioned in focus group discussions were frequently attributed to poor management and issues with leadership. Focus group participants considered that essential human, organizational, technical and environmental factors were necessary for establishing a safety culture. They indicated that they considered that the hospital leadership prioritised quantity over quality. Typical quotes from both male and female nurse discussions are described below.

> *"Safety to patients!? The priority is that the patient has the 'chemo' and go."* **(Nurse A Focus Group 6)**

> *"They don't want to know about mistakes so why should we tell them. They want the work done whichever way – wrong or right as long as it's done."* **(Nurse A Focus Group 2)**

3.7.5.1 Human factors

The low priority given to safety was reflected in other aspects of the staff's wellbeing. Nurses in particular felt unsupported by their management as described below:

> *"…but they don't look at his environment, his circumstances, ok. Now if you have a labourer and you want to employ him, let's suppose, any labourer, if you don't treat him well, do you think you can trust him. No, you won't trust him. Now if you employ someone, you need to take care of him, find out what his problems are and I mean all these people, they have families, they have problems, they have so much to worry about…. You solve the problems of your staff, and prepare a good emotional environment, train and then see"* **(Nurse B Focus Group 6)**

Low pay contributed to a general feeling of low self-esteem, resulting in nurses engaging in private work to supplement their salaries, leading them to neglect their tasks at the hospital. A typical quote from male nurse focus groups is detailed below.

> *"You hear them say, they give me so much and I will work for their money's worth and no more. In this type of work, if you don't have your conscience in place and don't have a sense of duty, and you work for the patient's benefit, I mean put the patient's benefit as number one priority, then you will never be able to work…. but they don't consider them for job promotions, incentives and allowances. They don't see how the nurse lives, their problems at home, all of that doesn't matter. Ok, in*

> *these current living conditions, is anyone blind to how expensive the food has become. Ok? but people end up doing extra work and they say we have so and so…. (meaning they have private jobs in other hospitals and centres)"* **(Nurse B Focus Group 6)**

3.7.5.2 Organizational factors

All focus group participants explained they were not aware of job descriptions. None of the participants in any of the healthcare teams had been given a job description but relied on being told what to do by others. Below are typical quotes:

> *"There is no job description and hence anyone can do anything they feel, hypothetically speaking, someone might come in and do any job"* **(Pharmacist B Focus Group 5)**

Focus group participants explained that personal intuition, work ethics, and word of mouth were used to inform staff of what was expected of them. They had no knowledge of work-based procedures and protocols. Below is a typical quote from male nurses' discussions.

> *"There is a job description of some sort. They tell you what you have to know. But I haven't seen anything in writing…. These are the code of ethics which has everything in it and the work regulations, regulations, code of ethics and performance; you tend to know what to do."* **(Nurse B Focus Group 6)**

The lack of job descriptions resulted in job role and tasks being left to the HCW's own interpretation, which meant that essential patient care was seen to be an extra burden and a source of stress. A typical quote from male nurse focus groups is shown below.

> *"…we can assist them (patients), explain to them how to keep clean, how to eat well, ... if there are extra things and the patient has to have wound dressings, they need investigations every hour, also someone wanting some drugs that have to be given at certain times of the day, or they may be someone requiring chemotherapy or things like that, then that can cause stress. But, I don't know we won't 'short-change' the patient and will do the best we can and everything that we are able to do for that patient."* **(Nurse B Focus Group 6)**

A doctor described how he thought the absence of job descriptions and appraisals prevented identification of incompetent members of staff.

"We don't have job descriptions or job appraisals. If there are job appraisals, certain management staff would have been found to be incompetent and stopped from working." **(Registrar D Focus Group 4)**

3.7.5.3 The work environment

Error-provoking work environments were discussed at length during all the focus group discussions. Busy and disorganized work environments were considered by most participants in all focus groups to contribute to errors, or events that might lead to errors. Below is a typical quote from a female nurse.

"*We used to have a table (paper record) where we recorded administration details. We use to draw that up ourselves but we don't do that anymore…. we used to record the drugs we give to patients… We stopped recording because the wards were getting too busy."* **(Nurse C Focus Group 2)**

Furthermore, busy and disorganized work environments were also considered to be a cause of tension to health care workers and conflict between doctors and patients. Below is a typical quote.

"Patients must know where to go and they should be given information and directions. During clinics, we get numerous interruptions from patients who want to know where the medical records are or where the lab is. We end up being short-tempered and snap at people and make errors. The patients as well get agitated. Simple measures like a functional information desk and directions could make life easier for everyone. ….. These things are simple and you don't need to carry out a study to identify them. We need a user-friendly hospital that is also subject to safeguards to improve quality." **(Registrar B Focus Group 4)**

Disorganized patient medical notes were identified as another cause of error, as illustrated below.

"I honestly can see how errors could occur when prescribing chemotherapy. The patient files are badly designed, the records are all over the place and they usually look like a stack of cards. I am sure that most doctors are not able to read the whole patient history before prescribing and hence tend to guess." **(Registrar C Focus Group 4)**

3.7.5.4 Resources

There was general concern about tools, equipment, availability of essential medicines, training and other quality systems that were identified as essential components of safe patient care. Deficiencies in equipment were identified by doctors as being caused by mismanagement of finances rather than scarcity of resources. A typical quote from a male doctor explained.

> *"…. The management were unable to manage the finances in an efficient way and money was squandered on issues which were not of priority. The management team should prioritize patient care and fix the radiotherapy machines…"* **(Registrar B Focus Group 4)**

Emergency medicines were not always available on wards and one doctor provided an account of how this resulted in a patient's death:

> *"Even when there are improvements, things don't last very long. About two years ago, I spoke with the chief executive of the hospital and the chief pharmacist about providing free emergency drugs for patients. We worked on a list of emergency resuscitation drugs and decided that we should place them in the doctors' mess so that they can be freely accessed. That system was working well for a while but suddenly last week, I discovered that I have no access to emergency drugs. I haven't been doing on call service for a while and I don't know when this system fell apart. A patient had a cardiac arrest and he died because I didn't have access to emergency drugs"* **(Registrar B Focus Group 4)**

Among the focus groups who handled chemotherapy, the nurses and pharmacists had concerns with regards to waste management, because they perceived that the current systems were sporadic and un-sustained. This is described in the examples below.

> *"How can we talk safety? Safety in chemotherapy, how is that? If there was safety, do you think the chemotherapy waste bin should be left lying about like this? Shouldn't be like this, should it? …… If you come in here, you see the bins overflowing with chemotherapy, the vials all over the surface and syringes lying about on the table and sometimes next to the patient in the bed."* **(*Nurse* A Focus Group 6)**

> *" …. e.g. we had a problem with waste management in the … department.....they just ignored it."* **(Pharmacist C Focus Group 5)**

Doctors and pharmacists had access to different training opportunities but this was *ad hoc* and was not based on a needs assessment. Focus group participants felt that few people had access to these training sessions and the benefits were not shared. Furthermore, the training had no direction because some doctors felt that they had a lack of basic medical training. In contrast nurses were unable to describe training opportunities available to them at the hospital. Instead individuals sought training from other organizations as described in the quotes below.

> *"there are lots of training but people go on courses and conferences and don't come back with feedback. People from the physics department go on many training days but that is because it is external"* **(Pharmacist C Focus Group 1)**

> *"Yeah that's fine, there's lots of training but what is it based on. I don't think that they have done a needs assessment to find out if there are areas of training that are more required that others and the training depends on personal initiatives. So, Dr X is keen on training and hence when he was responsible for training, there were regular training sessions. But usually people will go to the training session when it is available not when they need it"* **(Registrar A Focus Group 4)**

> *"The nurses need help with giving the 'chemo'. .....Even the preparation of the drugs is a problem to some nurses. They don't know what to dilute the drug with, dissolve in, or administer it in....."* **(Nurse A Focus Group 6)**

3.8 Discussion

This qualitative study was conducted among 24 HCWs to explore their perceptions about PSC and to identify its implications for current practice. To our knowledge this is the first study of its kind to be conducted in a cancer hospital in a developing country. Data collected in this study was mapped to Reason's (1997) seven components, essential to establishment of a safety culture. Overall, the safety culture at the cancer hospital was perceived to be poorly developed. HCWs reported feeling unsupported, were unaware of patient safety systems and tended to hide errors because they were convinced that errors would be either ignored or dealt with in a punitive manner. Moreover, a lack of essential safety systems contributed to medication errors, frustration and low morale among the staff.

Applying the MaPSaf as the framework for the current study enabled the identification of the cancer hospital's safety culture as perceived by HCWs. The key weaknesses identified were:

- An apparent absence of safety systems at RICK meant that the safety parameters developed by Parker (2009) as essential for PSC were rated by the participants consistently at the lower points on the scale.
- Error reporting systems are not accessible to HCWs and, in instances of sporadic error reporting, there was no feedback and hence learning from errors was seemingly absent.
- A culture of blame was shared among all HCWs leading to hiding of errors.
- Poor communication meant that teamwork was weak and team hierarchies were described as rigid.

Measuring PSC is important because it can both reveal how staff act towards safety incidents and identify areas of practice that require safety improvement (Nieva et al., 2003). A modified version of MaPSaF had been used to study baseline PSC maturity in a general medicine setting and track its development after implementing a safety intervention across three hospitals in Sweden (Ohrn et al., 2011). Similar to the study hospital, some departments from the three hospitals initially rated their safety culture at low PSC maturity. Implementing a Patient Safety Dialogue intervention, based on EWRs, improved PSC over a five year period, with a change of 78% in general patient safety from baseline (Ohrn et al., 2011).

3.8.1 Error Reporting and Learning

Findings from focus groups indicated that participants were unaware of systems of error reporting at the study hospital and when errors are reported, they are ignored, hidden or dealt with in a punitive manner. There are several consequences to this finding. Firstly, errors were not recognised by HCWs which meant that if an error occurred, corrective actions could not take place and patients would be at risk of increased harm. Secondly, because errors were not discussed, they were likely to be repeated in similar circumstances and thirdly, without formal error reporting, opportunities for learning from these errors in order to improve patient services were limited. It is not known whether error reporting systems exist in Sudan but there are published reports that Sudan Ministry of Health, in association with the WHO, Regional Office for EMRO, has established a patient safety

system (Abdallah, 2011;WHO, 2012;Siddiqi et al., 2012). A study carried out in collaboration with the WHO across seven member countries of EMRO, including Sudan, aimed to set up the Patient Safety Friendly Hospital Initiative as a pilot to enable member states to establish a Patient Safety programme (Siddiqi et al., 2012). The pilot involved nominating a hospital which was subsequently assessed for level of patient safety according to five domains: leadership and management measures, patient and public involvement measures, safe evidence-based clinical practice measures, safe environment measures and life-long learning measures. After completion of the assessment, the nominated hospital was given suggestions and recommendations on how to improve the total score, with a re-assessment after a specified period of time. The authors recommended that healthcare systems in member states should repeat this process in ten hospitals as a first step towards applying this initiative nationally. However, there has been no further published information to identify if this initiative was implemented nationally. HCWs at the study cancer hospital were not aware that such a system existed in their hospital.

A review of 25 studies conducted in a Middle Eastern country, Iran, did not identify awareness about error reporting systems as a barrier to error reporting (Mansouri et al., 2014). However, none of the studies aimed to assess staff awareness about the existence of reporting systems. Research conducted in Australia and the US has shown that some HCWs may not be aware of the presence of an error reporting system even when this was in place (Evans et al., 2006;Pronovost et al., 2003). A survey conducted in six South Australian hospitals among 186 doctors and 587 nurses revealed that 1.7% of staff were unaware of error reporting systems at their hospitals and that the main barrier to reporting was lack of feedback (Evans et al., 2006). Fewer doctors (46%) than nurses were aware of error reporting systems in a survey conducted among over 600 staff comprising doctors, nurses, pharmacists, managers and administrators in a 900 bed US hospital (Pronovost et al., 2003).

HCWs have been reported to informally report and discuss errors with colleagues (Wu Aw, 1991). A survey of 254 house officers training at a US based academic tertiary care centre found that 54% of doctors discussed their errors with the senior clinician, even in the absence of a formal error reporting system (Wu Aw, 1991).

Focus group discussions in the current study revealed that when near misses occurred at the cancer centre, the individuals concerned did not identify a need for reporting. This is contrary to the requirements of achieving patient safety because HCWs share a common

goal to provide patients with safe medical care and error reporting is essential in identifying safety risks (Cohen, 2000). Furthermore, reporting of near misses is an essential component of PSC (Reason, 1998). Near miss reporting has been identified in industry as essential in identifying error prone situations and correcting them before an error occurred (Barach et al., 2000). Near misses are not reported in the study hospital and it can hence be inferred that errors are likely to be repeated placing patients at considerable risk of harm from ADEs.

A general perception which emerged from the healthcare team discussions was that error reporting could lead to breach of staff confidentiality because, from their previous experiences when errors were discovered by other staff, such errors were either disclosed or discussed in public. If this manner of error disclosure was the norm at the cancer centre, it is likely to be a strong deterrent to reporting errors. Confidentiality is an important aspect in error reporting (Barach et al., 2000).This finding was similar to other studies in developing countries where researchers in Saudi Arabia identified that breach of confidentiality led to fear of reporting among HCWs (Alahmadi, 2010).

An important aspect for reporting errors is elimination of a blame culture (Leape, 1994). A culture that fosters blame and punishment discourages reporting of errors, and hence hinders learning processes and the development of a safety culture (Nieva et al., 2003). The first step required to improve patient safety was to build a safety culture (NPSA, 2004b) where HCWs understand the importance of reporting errors in a just environment which is free from blame (Reason, 1998).

Removal of the blame when dealing with errors can lead to improved incident reporting and learning (Womer et al., 2002). In a cancer centre in the USA, a multidisciplinary patient safety intervention was carried out among 27 nurses in order to improve error reporting. Prior to the intervention, a disciplinary procedure recommended that nurses, involved in errors, receive written warnings or even be suspended. The intervention involved introducing an anonymous error reporting system in conjunction with feedback meetings where solutions to the reported errors and near misses were discussed. This resulted in an increase in reported near misses and prevented errors and a decrease in actual errors (Womer et al., 2002).

In order to ensure safe medical care, the establishment of an error reporting system in a Sudanese cancer hospital is a key component, the responsibility of which lies with both the state and the individual health care organization (Kohn, 2000;NPSA, 2004b;WHO, 2005b). Individual HCWs involved in errors as well as organizations should learn from error and

construct systems that capture, reduce and mitigate those errors should they reach a patient (Wu Aw, 1991). Such a system is essential for the study hospital because it was evident from the focus group discussions that errors do occur, were repeated and many were preventable. The anonymous error reporting system established by Womer and colleagues (2002) consisting of a box where incident forms, scribbled notes, copies of orders and medication labels were deposited. A similar safety system, in line with guidelines from the previous NPSA *"Seven Steps to Patient Safety*" could be implemented within the limited resource setting of the study hospital.

3.8.2 A Culture of Blame

During the focus groups participants provided a number of accounts of situations where errors were discussed. However, a culture of blame was seemingly prevalent among the HCWs who themselves considered that part of error management was to punish the individuals involved or in order to reduce the incidence of errors. A culture of blame is not conducive to learning from errors (Singer et al., 2003), because HCWs will hide errors in order to avoid punishment, reprimand, disciplinary action and being labelled as incompetent (Nwozichi, 2015). However, this is not unique to the study setting but *"blame"* was the common manner of error management in the years before the IOM published *"To err is Human*" (Kohn, 2000). An example of this occurred in a large cancer hospital in the USA, where a cancer patient died as a result of been given the wrong dose of chemotherapy (Conway et al., 2005). The incident was highly publicised and the eighteen nurses who were involved were sanctioned by the state board for their role, without an investigation being carried out (Grant, 1999). In response to the disciplinary action taken against the nurses (Grant, 1999), Lucien Leape wrote an article in the Boston Globe stating that this decision *"is misguided, inappropriate, and harmful"*, explaining that punishment in the absence of wilful neglect or negligence would not improve the performance of the individuals involved, deter others from similar errors or protect the patients from the effects of these errors (Leape, 12 Jan 1999).The cancer centre involved undertook a detailed investigation of the incident to identify service gaps. A number of safety systems were introduced, including a non-punitive error reporting system and chemotherapy pre-printed templates, that reduced the errors of ambiguity or incompleteness seen with handwritten prescriptions (Dinning, 2005). System improvements and improvement of patient safety culture contributed to reducing the incidence of chemotherapy-related safety events from 3.4

incidents per 1000 doses to 1.7 incidents per 1000 doses, over an eight year period, with no fatalities (Conway et al., 2006).

Blame cultures can foster a blame cycle where the management feels frustrated at staff not adhering to rules and staff feel devalued (Reason, 1990). This was evident in the current study, where staff often felt that management ignored their needs and did not provide them with the support they deserved. One example was that nurses left their tasks unattended to gain extra income from other hospitals, another was the general disregard of documentation, suggesting that staff felt these rules were not important. Documentation is generally well known to be poor in low- and middle-income countries (WHO, 2010), and a culture of non-adherence to medical record keeping was reported in other African countries (Pirkle et al., 2012). Recording in patients' notes was perceived as time-consuming and that accomplishing the medical task was more important (Pirkle et al., 2012). However, medical records are an essential element of patient care, the absence of which can undermine patient safety (Bradley et al., 2012).

Furthermore, nurses would intentionally violate some procedures because they seemed to lack the understanding underscoring the importance of these procedures. An example was when they missed giving the patient their intravenous fluids despite these being clearly written in the chemotherapy administration instructions. This may have significant clinical implications for the patient. Drugs such as cisplatin and methotrexate are renally cleared and patients must receive appropriate hydration to enable efficient excretion, without which patients are at high risk of toxicity (Reed, 2008). A similar situation was identified at an African hospital (Kotagal et al., 2009). In response, an intervention that targeted process improvement was implemented, where time to give drugs was improved by 95% (Kotagal et al., 2009). Furthermore, the authors reported better patient outcomes and increased staff morale at the end of the study (Kotagal et al., 2009).

According to participants' discussions, daily patient care was handled by relatives and caregivers, and nurses viewed their involvement in such tasks to be an extra burden, rather than their responsibility. Similar findings have been reported in research from developing countries. Nurses in Bangladesh were reported to spend less than 10% of their time in direct patient care. Interviews from key informants from nurses, doctors, patients, carers and hospital workers confirmed that nurses view direct nursing care as the responsibility of carers because of cultural issues where females are not allowed to touch males, and

professionals perceived that dealing with patients' personal hygiene would reduce their status in society (Hadley et al., 2007).

Errors described by focus group participants in the current study, were perceived to be caused by procedural violations. Violations are not commonly described in the medical literature and this may be due to a number of reasons. Most importantly, a number of AE studies are based on record review, which makes ascertaining violations difficult. Secondly, findings from incident reporting systems are unlikely to isolate such incidents, and finally, reporting violations may expose the individuals involved to accusations of negligence and misconduct (Amalberti et al., 2006). Consequently, most landmark studies in patient safety did not mention violations (Classen et al., 1997;Baker et al., 2004;Leape et al., 1991) in their reports. The exception being one study conducted as part of the Quality in Australian Healthcare Study which listed two descriptions of errors categorised as violations of rules (Wilson et al., 1999).

In instances where written instructions are ignored, in a just culture, HCWs who intentionally ignore safety procedures should be held accountable for their actions (Wachter et al., 2009). However, in the study setting this approach may present some difficulties because to determine if an individual health care worker is culpable for the error, a number of factors need to be considered (Reason, 2004). Firstly, a decision needs to be made if the individual involved had intentions of malevolence, sabotage or harm. Secondly, the individual involved should be assessed for substance abuse. Thirdly, individuals involved should have received appropriate training, clear SOPs and task related guidelines. And lastly, the circumstances surrounding the errors should be assessed to determine if, under similar conditions, this error would be repeated. Findings from the current study reveal that HCWs had little awareness about SOPs and had little guidance. Furthermore, training in medication processes was seemingly absent. A just culture may only be implemented in workplaces where the level of safety is mature and safety systems are in place (Wachter et al., 2009).

3.8.3 Teamwork

A combination of ineffective communication, lack of job descriptions and team dynamics contributed to an overall perception that teamwork was poorly developed at the cancer centre. It is not surprising that teamwork among staff who have poor communication is poorly developed. This finding was in contrast to findings from research in similar healthcare

settings. A survey, using HSPOSC among 6,807 HCWs in Lebanon, had the highest positive composite scores for teamwork between staff in units but it was the lowest between units (El-Jardali et al., 2011). Teamwork between units has also been shown to be poor in early healthcare studies in western cultures, whereas aviation teams who worked in organizations with a well-established safety culture scored favourably for teamwork composites (Sexton et al., 2006). Development of teamwork habits, behaviours and skills has the potential to reduce medication errors and improve communication (Risser et al., 1999).

Poor communication has several implications for patient care because it can lead to misunderstandings when treating patients and low morale among HCWs. In contrast, good communication has been shown to be associated with improvements in patient safety incidents (Alfredsdottir et al., 2008). Nursing staff in the focus groups implied that they accepted hierarchical communication, whereas doctors believed this approach in communication, unacceptable. This could be interpreted using the Power Distance Index (PDI) which places the Sudanese society on a high PDI (Hofstede et al., 1991). PDI is the degree to which the less powerful members of an organization accept or expect that power is distributed unequally. Therefore groups with high power distances accept and expect hierarchies where everyone has a rigid level (Hofstede et al., 1991) . These findings were confirmed from work conducted in Egypt where a similar culture exists. A total of 369 healthcare providers from a group of university hospitals were surveyed, using an Arabic translation of the AHRQ's HSOPSC, which identified communication openness and communication about errors to have composite scores of less than 50% (34.6% and 39.7% respectively). A positive correlation between team communications and PDI was identified in a survey of 600 Japanese doctors and nurses (Itoh et al., 2002). Communication among and between teams can be improved using PSC interventions such as checklists. Implementation of a surgical checklist at a university hospital in the UK helped nurses to speak up about safety incidents, improving patient safety (Etchegaray et al., 2014). Similar interventions have documented success in Sudan. Unpublished work has shown that implementation of the WHO safe surgery checklist improved communication and contributed to better team relations in operating theatres (Abdallah, 2011).

Communication specifically among nurse focus group participants was affected by poor trust and allusions of bribery. Although efforts were made during the focus groups to invite nurse participants to give examples of occasions when they had witnessed or were involved bribery, these were unsuccessful. The literature suggests that HCWs in poor income

countries may become involved in bribes, and the earnings may be used to supplement their low incomes (Lehmann et al., 2008). A survey of 272 patients and HCWs from public and private healthcare facilities in a developing country revealed several examples where relatives were asked to pay HCWs for services known to be free of charge (Tibandebage et al., 2005). Efforts to reduce this behaviour can be achieved by effective management, supervision and clinical auditing (Tibandebage et al., 2005) .

3.8.4 Leadership

A finding common to all focus group participants was poor access to appropriate training and equipment. Furthermore, HCWs worked in environments that were conducive to error. Qualitative research conducted in developing countries has identified that lack of equipment is common in healthcare facilities. Examples were described, similar to the current study, where patients had died because of poor access to necessary medical equipment and medicines; for example, an interview study of 57 HCWs from two East African hospitals described similar work environment situations where theatre areas were outdated and poorly furnished, and where work environments were busy (Aveling et al., 2015).

Busy work environments were mentioned as a source of error in the current study but no examples of how interruptions affected errors were described. However, interruptions have been identified as a source of medication errors in delivery of cancer chemotherapy (Schulmeister, 1997). Womer and colleagues (2002), at a large cancer centre, introduced a note system to reduce interruptions in the busy work environment as part of a wider patient safety improvement strategy. Interruptions were reduced from 27.6 per shift to 13.8 and, together with other safety improvements, the centre achieved an 84% reduction in error rates (Womer et al., 2002). Busy work environments cannot be eliminated, especially because the study hospital is the major referral centre for Sudan, but as the findings suggest there is a need to design a system which manages the large number of patients attending the hospital and ensures that safe medical care is delivered.

Work-based training has been identified as essential to ensure accuracy of work and has been shown in a randomised controlled trial, conducted among final medical school graduates in a German university, to reduce the incidence of drug-related problems (Celebi et al., 2009). Given the risks associated with the use of cytotoxic chemotherapy (McDiarmid, 2006;Cousins et al., 1994), safety for both patients and hospital staff can be assured if

appropriate competency-based training programmes are in place (NPSA, 2010b;ASHP, 2002). In the US, legislation exists to ensure that guidelines for handling chemotherapy are implemented in healthcare settings (Eisenberg, 2012). It follows that working in these high risk conditions without the appropriate training may be considered unacceptable (ASHP, 2002)

A qualitative study that compared the implementation of a surgical checklist in two hospitals, one in the UK where health services are well-developed and another in a low income sub-Saharan country, found that compliance was higher in the former hospital. The authors identified that the obstacles to implementation of the checklist were: resource limitations, poor documentation, poor team dynamics and communication, lack of accountability, policies and institutional support. They identified that safety interventions are difficult to implement in the absence of institutional support and staff motivation (Aveling et al., 2013). Hence, in our hospital, the organization as a whole is responsible for addressing deficiencies in systems essential for establishment of a safety culture. Leaders are instrumental in shaping the organization's culture because their actions, rewards and punishments communicate their priorities to staff. Therefore if the leader is focused on safety, they would direct resources to development of safety systems, encourage and reward staff who adhere to these systems (Westrum, 2004).

The WHO acknowledge that doctors, nurses and pharmacists place patient care as a priority and often work under great pressure to improve patient outcomes; however, without investing resources into quality of care, failings of these individual attempts can occur. The support from the administration in a well-known cancer centre in the US has provided the means and leadership to steer the cancer centre to reach an exemplary level of patient safety (Conway et al., 2005;Womer et al., 2002). In the current study setting, the focus group discussions would suggest leadership has not placed safety as a priority and hence staff feel untrained, unequipped, unsupported and have low morale, which has the potential to compromise patient outcomes.

3.9 Limitations

The current study has several limitations. Firstly, the study attempted to measure patient safety culture in an organization where safety systems were deficient and therefore HCWs consistently scored all dimensions of the MaPSaF at the lower levels. However, even in the absence of a PSC, the use of the MaPSaF would probably contribute to raising awareness

about PSC issues and stimulate discussions about gaps in the services and possible interventions. Secondly, this apparent absence of reporting systems meant that analysis of focus group data were not feasible using the MaPSaF framework. However, the use of Reason's framework was successful in mapping the themes emerging from these exercises.

The third important limitation was the difficulty in recruiting staff to participate in the study. This resulted in considerable lag in time between focus groups. Potential participants were approached to take part in the study and individuals had accepted and consented but did not attend the pre-arranged focus group date and were not contactable by telephone. It was clear that the social norm of HCWs at the cancer hospital prevented them from simply declining to participate in the study. Moreover, it can be inferred that the blame culture contributed to staff's anxiety about discussing errors and prevented participation in the study. Although focus groups were run with some lag time, it is unlikely that this factor will have had an impact on the design of the study because there were no major changes in work systems during the whole study period. This was confirmed by the consistent findings among the groups.

The qualitative nature of this study may be an important factor in generalization of findings, because a small and non-representative sample of HCWs was recruited in the study. However, the purpose of qualitative studies is not to be representative and, in the current study, they were used to identify service gaps and highlight areas that required further research.

3.10 Future work

Considering the findings of this study, further work was undertaken to identify the frequency and types of medication errors associated with chemotherapy and explore the possible causes of these errors. It is expected that findings from these studies would offer a better understanding of the impact of the absence of PSC elements on the chemotherapy process. Furthermore, these studies are expected to involve a wider number of staff and hence make the findings of the study more generalizable to the cancer centre under study.

There is a wealth of published work on the success of interventions to improve PSC; however, most were conducted in western countries where work environments and culture are different to the current setting. There is a need to design an interventional study to address some of the gaps identified in this study.

3.11 Conclusions

Findings from the current study highlight important gaps in service provision to cancer patients. Errors and violations were common but were mostly ignored and, when highlighted, the individuals were dealt with in a punitive manner. Teamwork was hampered by rigid hierarchies, and communication within teams and between teams was non-conducive to a PSC. There seemed to be an absence of leadership to drive PSC, demonstrated in the absence of training, poor resources and the apparent absence of safety systems.

PSC is embedded in the values, assumptions and the norms of the organization which requires the implementation of supportive structures and processes. Hence, few of the obstacles identified by focus group participants can be addressed with single short term interventions or without the mobilisation of resources. Evidence from the literature underscores the importance of leadership in championing changes required for establishing a safety culture (Frankel et al., 2006). However, an important barrier to culture change is the unawareness of patient safety gaps. Leaders need to be accountable and aware of safety gaps in their organizations and this can be achieved by establishing systems of error reporting at the team level and overseen by a multidisciplinary committee composed of medical, nursing and pharmacy managers. Regular monitoring and feedback from errors may have an important impact on improving safety culture at the centre. Firstly, error reporting would determine gaps in service provision and improve communication within teams and across teams. Secondly, regular monitoring and feedback would possibly stimulate discussions essential in devising innovative interventions tailored to the needs of HCWs at the cancer centre and patient safety. Thirdly, findings from these exercises may be used as a tool for advocacy at the state level. The implementation of interventions requires the mobilisation of resources and supervision from the ministry to ensure its sustainability. In conclusion, considerable system changes are required to improve patient safety but can be achieved using simple measures that require the engagement of leaders at the team level, organizational level and state level.

CHAPTER FOUR

4 FREQUENCY, TYPES AND CAUSES OF CHEMOTHERAPY PRESCRIBING ERRORS

4.1 The Prescribing Process

The process of writing a prescription is complex and involves sound clinical reasoning and careful judgement (Haas et al., 2012). Decision making during the prescription process is influenced by a number of factors: maximising benefit, respecting patients' choices, cost-effectiveness and minimising treatment-related risks (Barber, 1995). Hence, in order to ensure these factors are met, several steps should be taken before issuing a prescription. The prescriber should 1) reach the appropriate diagnosis, 2) assess whether or not the patient requires an intervention or treatment, 3) choose a medicine, dose, dosage form and protocol appropriate for the patient and 4), lastly, engage with the patient in a discussion to ensure that the medicine chosen is acceptable, that they understand the dosage instruction, the potential adverse effects and what monitoring is required.

There are no international standards governing the contents of a prescription, although every country has its own regulations. However, the WHO states that all prescriptions should contain clear information in order that the medicines are dispensed accurately (Vries et al., 1995). The seven components identified by WHO are summarised in Figure 4-1.

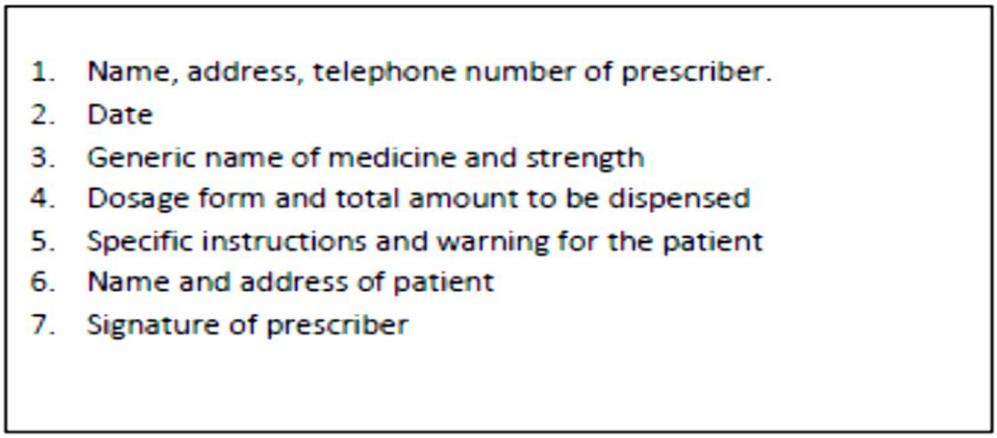


Figure 4-1 Components of a prescription adapted from Vries et al (1995 p 66-69)

4.2 Prescribing errors

Medication errors can contribute to up to 29% of hospital admissions (Morimoto et al., 2011) and 15% of in-hospital adverse events, half of which are preventable (de Vries et al., 2008). Preventable adverse events can occur at the prescribing, dispensing or administration stages of the medication process, with one third due to prescribing errors (Morimoto et al., 2011). Various definitions of prescribing errors have been adopted in

medication safety research (Lewis et al., 2009), but the most robust definition developed by Dean and colleagues (2000) has been used by nearly one fifth of those studies. A consensus on a systematic definition of prescribing errors was reached using two-stage Delphi technique where thirty-four healthcare professionals described a clinically meaningful prescribing error as (Dean et al., 2000):

> *"a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice." (Dean et al 2000 p 235)*

Research into the scope of prescribing errors has found no consistency between studies in the frequency or nature of errors (Lewis et al., 2009). The first systematic review of prescribing error research, which included 65 studies, revealed that the rate of errors could be 2-14% or 8-227 errors per 100 admissions (Lewis et al., 2009). This review reported that variability has arisen because studies used different methods of error detection and different definitions, hence findings from prescribing error studies are difficult to interpret and compare. For example, process-based errors would identify higher rates than outcome-based studies which would only identify prescribing errors that resulted in patient harm. The review revealed that most studies were conducted in western countries with a few (n=5) conducted in countries from Asia and the Middle East. More than 80% of the studies used a prospective design, and most investigated process rather than outcome. Most studies derived their data from errors identified by pharmacists during routine practice. Dosage errors were the most commonly identified, primarily with antimicrobials (32%), cardiovascular drugs (17%) and central nervous system and gastrointestinal drugs (8%). A number of studies reported that recently qualified doctors, in comparison with senior doctors, contributed the most to prescribing errors (Lewis et al., 2009).

4.2.1 Types of prescribing error

As prescribing is complex, errors can occur at more than one component of the prescribing process. The commonest errors occur when deciding or calculating a dose (Winterstein et al., 2004). Winterstein and colleagues (2004) analysed 321 incident reports associated with medication errors occurring in a US tertiary hospital. Their analysis revealed that overdoses were more common than underdoes and among three common prescribing errors were omission of a medicine which is clinically indicated and wrong choice of medicine. Omission

errors were more common among newly admitted patients, in particular (Franklin et al., 2011). Other errors reported in the literature include; wrong frequency (Bates et al., 1995a), transcription errors (Fahimi et al., 2009), failing to order appropriate monitoring for the medicine (Benkirane et al., 2009), drug interactions and prescribing a drug to a patient who is allergic (Runciman et al., 2003).

4.2.2 Causes and contributory factors associated with prescribing errors

Prescribing errors are associated with a number of active failures, error-provoking conditions and latent factors. A review of 16 prescribing error studies identified that active failures were mostly associated with KBMs, slips and lapses (Tully et al., 2009). Rule violations were less common but have been reported in the literature (Buckley et al., 2007). An observational study of 263 prescriptions in a paediatric ICU identified that although knowledge-based mistakes are more common (46.2%), rule violations (30.8%) can also occur. An example of a rule violation was the prescribing of analgesics without appropriate titration (Buckley et al., 2007).

Each active failure occurs under a number of error-provoking conditions which may be associated with the individual prescriber, the prescribing task, the working environment, healthcare team and the patient (Tully et al., 2009). Inadequate skills and knowledge, heavy workload and staffing were the most common error-provoking conditions (Dean et al., 2002a). Dean and colleagues (2002) interviewed 44 doctors to identify the factors associated with prescribing errors in a UK based teaching hospital. A combination of semi-structured interviews and questionnaires were used to identify contributory factors leading to errors. They also identified factors associated with the work environment, where busy doctors were commonly interrupted by patients and other members of the healthcare team. The authors reported that doctors had poor appreciation of the prescribing task, possibly due to insufficient teaching during undergraduate medical education.

The low importance attached to transcribing was also reported as a latent factor associated with prescribing errors (Coombes et al., 2008). A semi-structured questionnaire was used to identify factors associated with prescribing errors among fourteen newly qualified doctors in an Australian hospital. Doctors also attributed some of their errors to a number of error-provoking conditions such as inadequate supervision within the team, complex patients, the mental wellbeing of the individual doctor, availability of protocols to aid the

prescribing task and environmental factors such as working long hours (Coombes et al., 2008).

Since lack of knowledge has been linked to prescribing errors, junior doctors have been commonly implicated in those errors (Coombes et al., 2008;Dean et al., 2002a). However, conflicting findings have been reported from other studies, because some studies failed to adjust error rates to the number of prescriptions written by junior doctors (Lewis et al., 2009). A retrospective review of over 8000 prescriptions in a US hospital revealed that junior doctors wrote more than 60% of prescriptions in comparison with other grades (Hendey et al., 2005). First year postgraduate doctors had higher error rates when compared with other grades during overnight and on call periods but error rates were similar otherwise (Hendey et al., 2005). These findings have been confirmed by another large study undertaken in a group of UK hospitals (Dornan et al., 2009). The researchers used methods commonly employed in prescribing error research (Lewis et al., 2009), by asking pharmacists to record prescribing errors encountered in their daily review of medication cards and prescriptions. Data were obtained from pharmacists' prescription screening of 124,260 medication orders, collected monthly on seven consecutive months, with an error rate of 8.9%. During data collection period, newly qualified doctors in their first year were responsible for prescribing most the medications (50,016) and consultants were responsible for prescribing the least number of medication orders. Although the rate of errors committed by newly qualified doctors was highest among the other prescribers, it was lower than those committed by second year doctors who had a prescribing error rate of 10.3%.

4.2.3 Barriers to prescribing errors

The process of prescribing should improve patient outcomes but is in itself complex, mainly due to the numerous factors that have to be considered before reaching a final decision about the drug, dose, duration and route (Aronson et al., 2006). The WHO highlighted that inadequate teaching of prescribing in medical schools compromises the ability of doctors to write appropriate prescriptions (Vries et al., 1995). Communication failures have been recognized as playing a major role in prescribing errors where the safety culture of the medical institution meant that nurses and junior doctors felt disempowered to question senior staff (Sexton et al., 2006). Safeguards are important in medical institutions and in this study, doctors, identified pharmacists as important defences because they intercepted errors before reaching patients. Pharmacists undoubtedly have a positive impact on

reducing medication errors and have been shown to contribute to a reduction of 66% of prescribing errors (Leape et al., 1999).

The role of pharmacists in rectifying errors was explored in a comparative study that also identified the incidence of errors in three NHS organizations (Franklin et al., 2011). Similar methods to previous prescribing error research (Dean et al., 2002b) were used which involved collecting data from pharmacists' routine ward-based prescription screening at three NHS hospitals. Out of 6,605 prescriptions, 1025 errors were identified, of which omission errors were the commonest, followed by dose errors and incomplete prescription. Errors were more common in the organization where pharmacists were least likely to intervene and rectify a prescribing error. Pharmacists were able to intercept most errors before they reached patients and a mean of only 0.9 doses were administered or omitted before the prescribing error was rectified (Franklin et al., 2011).

4.2.4 Studies of prescribing errors in the African and East Mediterranean (AFRO/EMRO) WHO region

Since the early 1990s substantial progress has been made by western countries to identify the effect and factors leading to prescribing errors on patients, but those from the developing world have yet to gain momentum. Assisted by the WHO, the African and East Mediterranean Adverse Events Study (Wilson et al., 2012;WHO, 2011a) , showed that ADEs contribute to 4% of patient harm. This rate is relatively low in comparison with studies in western countries 12%- 20% (de Vries et al., 2008) which may indicate that the use of medicines in the studied countries was not as widespread as in western countries. However, the impact of AEs in these countries is more significant because they are associated with higher rates of death (30% vs 8%) when compared with western studies (Vincent, 2010) and higher preventability (83%). Since preventable AEs have been associated with system-related factors which lead to errors (Rothschild et al., 2005) it can be inferred that medication errors and hence prescribing errors can be common. Studies of medication errors in the region have confirmed that prescribing errors (47%) are the most common among those errors (Dibbi et al., 2006).

However, evidence from the region on prescribing error in hospitals shows a considerable degree of variability (7%-100%) because studies each used a different definitions of error (Table 4-1), categories of error, study design (Table 4-2) and settings (Agalu et al.,

2011;Alagha et al., 2011;Al-Dhawailie, 2011;Al-Hajje et al., 2012;Al-Jeraisy et al., 2011;Dibbi et al., 2006;Irshaid et al., 2005;Yousif et al., 2011;Arulogun et al., 2011).

The definitions used to study prescribing errors varied greatly (Table 4-1) and some studies did not state an error definition (Al-Dhawailie, 2011;Arulogun et al., 2011;Yousif et al., 2011). For example, a retrospective analysis of prescriptions in Saudi Arabian hospitals used the WHO definition for prescribing errors which considered all elements of a prescription, including the telephone number of the prescriber and the address of the patient (Irshaid et al., 2005). Consequently, 100% of the 3796 prescriptions analysed contained at least one error (Irshaid et al., 2005). Another study that used a more commonly adopted definition in prescribing error research (Dean et al., 2000) reported a much lower error rate (Al-Hajje et al., 2012). In the study, data were collected from seven hospitals across Lebanon, and targeted patients who were newly admitted to non-obstetric wards. Data collectors reviewed the first ten patients who were admitted to the wards and extracted clinical data from the files as well as prescription details. In total, the researchers reviewed 1826 prescriptions for 313 patients and identified that 40% of prescriptions had at least one error. Unlike previous research, which identified that dose errors were more common, findings from this study showed that lack of monitoring parameters was more common (20%) in comparison with dose errors (6%).

The category of prescribing error also varied among studies from the region. For example, studies that reported on legality of prescription reported missing date and patient details (52.5%-99.9%) as the most common type of error (Arulogun et al., 2011;Yousif et al., 2011). Arulogun and colleagues (2011), used retrospective study designs to identify errors among 1866 prescriptions and mainly identified omission errors and, since both studies had no access to the patient clinical details, clinical errors were in the minority.

Table 4-1 Definitions used in prescribing error studies conducted in the AFRO/EMRO region

Author/ year	Definition of prescribing error
Irshaid 2005	A prescription should contain: name and address of the prescriber with telephone number, date of prescription, name and strength of drug, dosage form and total amount, information for label, prescribers' initials or signature, name and address of patient (age if child or elderly) (Vries et al., 1995)
Debbi 2006	Not reported
Agalu 2011	A deviation of medication prescribing from standard practices (as indicated in national standard treatment guidelines, textbooks, handbooks, and software) excluding dosage form errors, illegible hand writing, and failure to authenticate the prescription with signature and/or date.
Arulogun 2011	Not reported
Al-Dhawalie 2011	Not reported
Al Jeraisy 2011	An incorrect or inappropriate drug selection (based on indications, contraindications and other factors), dose, route, rate of administration, or frequency. A prescribing error also included illegible handwriting, an incomplete order (missing the dose, route, or frequency), incompatibility, incorrect instructions for using the drug product, and the use of non-standard nomenclature or abbreviations that requires further interpretation.
Yousif 2011	Legibility, completeness, abbreviations, changes, poly-pharmacy, refilling order, the identity of the prescriber, instructions to the patients and pharmacists, drug-drug interactions and adequacy of the prescriptions
Al- Hajje 2012	A result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice (Dean et al., 2000)

Table 4-2 Study design of research on prescribing errors in the AFRO/EMRO region

Author/ year	Country	Setting	Study design	Sample size	Error Frequency (%)	Most common prescribing error
Irshaid 2005	Saudi Arabia	GH	Retrospective prescription review	3796	100	contact details of prescriber, address and weight of patient
Debbi 2006	Saudi Arabia	GH	Retrospective record review	10,000	18	Wrong dosage strength 34.8%
Agalu 2011	Ethiopia	ICU	Prospective pharmacist screening	398	52.5	Wrong combination 25.7%
Al-Dhawalie 2011	Saudi Arabia	TH	Prospective pharmacist screening	1582	7.1	Wrong strength 34%
Arulogun 2011	Nigeria	TH	Retrospective prescription review	1866	76.3	Prescription illegitimate- missing date and age of patient
Yousif 2011	Sudan	PH, PrH, DC	Retrospective prescription review	2000	99.9	Patient's demographics 97.2%
Al- Hajje 2012	Lebanon	7 PH and PrH	Prospective record review	1826	40	Failure to state monitoring 20%
Al Jeraisy 2011	Saudi Arabia	PICU	Prospective pharmacist screening	2380	56	Dose errors 39%

Abbreviations: DC: doctor's clinics, GH= general hospital, ICU: intensive care unit, PH: public hospital, PICU: paediatric intensive unit, PrH: private hospital, TH: teaching hospital

Other errors were missing dose, dose frequency and dosage form (23.8%), errors of style including illegal abbreviations and illegible writing (18.8%), errors of dose (4.9%) and irrational use of medicines (0.8%), which were errors that included the wrong choice of medicine, and the use of Latin abbreviations (Arulogun et al., 2011).

One category not seen in western studies was the use of trade names (85%), which was very common in a Sudanese study (Yousif et al., 2011). The use of trade names in prescribing is discouraged by WHO in attempts to rationalise prescribing and is an indicator of Rational Use of Medicine (RUM) (Awad et al., 2007). RUM was defined as:

> "*patients receive medications appropriate to their clinical needs in doses that meet their individual requirement for an adequate period of time and at lowest cost to them and their community" (Awad et al 2007 p2).*

In general, prescribing error categories such as date and missing patient address are not defined as errors (Dean et al., 2000) and have not been included in most prescribing error research (Lewis et al., 2009) because they were found to have minimal impact in patient outcomes (Lesar et al., 1990).

In comparison, a study that used error categories common to other prescribing error research (Franklin et al., 2011;Lewis et al., 2009) identified different error types (Al-Dhawailie, 2011). Researchers analysed data collected by pharmacists during routine screening of 1582 prescriptions in a Saudi university hospital. Among the prescriptions included in the study, 7% contained an error. The most common type of error was wrong strength (35%), followed by wrong frequency (23%), wrong dose (12%) and wrong patient (4%). Unlike other prescribing error research in the area, the authors did not report on omission errors associated with patient demographics or prescriber identity (Al-Dhawailie, 2011).

Variations in study design meant that studies reported on other findings such outcomes, potential severity of errors (Al-Jeraisy et al., 2011) and contributory factors (Yousif et al., 2011). AL-Jeraisy and colleagues (2011) analysed data collected prospectively by pharmacists' screening of 2380 orders in a paediatric ICU in a Saudi Arabian hospital. The researchers reported that among prescriptions with errors (56%), those that had the potential to cause harm were in the majority (78.8%). However, the authors reported that medical records were not available for pharmacists and it was unclear what methods were used to assign harm (Al-Jeraisy et al., 2011). On the other hand, a mixed methods study was

able to report on contributory causes associated with prescribing errors (Yousif et al., 2011). A study identified from Sudan involved the analysis of 2000 prescriptions presenting at pharmacies from hospitals, doctors' clinics and primary care centres in the Wad Madani area (Yousif et al., 2011). Apart from the tool used, researchers published little information about methods used and validation techniques. A structured questionnaire was used to explore prescribing habits and contributory factors associated with errors among 155 doctors. Doctors revealed some causes of error similar to western studies (Dornan et al., 2009) such as time work pressure (57.5%). But others appeared to be unique to the area because over half of the participating doctors stated that the choice of drug prescribed was influenced by patient pressure (Yousif et al., 2011).

One study reported medication error related deaths (Dibbi et al., 2006). A retrospective review of 10,000 medical records of hospitalized patients at a hospital in Saudi Arabia revealed that medication errors occurred in 26% of the patients (Dibbi et al., 2006). Unlike other studies in the region 26 medication related deaths were reported of which 30% (n=8) were due to prescribing errors.

4.3 An overview of chemotherapy prescribing

Cancer is becoming an important cause of morbidity and mortality in Sudan, with nearly 10,000 new patients diagnosed every year (Saeed et al., 2014). There has been a steady increase in the number of cancer patients diagnosed in Sudan and other developing countries, with a notable increase in prescriptions for cancer chemotherapy. Increase in cancer cases in developing countries are mainly caused by adoption of a western lifestyle with poor environmental control (Jones, 1999). Most cases present at advanced stages (Hamad, 2006;WHO, 2002a) where the use of chemotherapy constitutes an important mode of therapeutic management (Carlson et al., 2003;Anderson et al., 2008) In addition, evidence from developing countries has shown that chemotherapy contributes to prolonging survival in patients with cancer (Bonadonna et al., 1981;EBCTCG, 2005). Furthermore, developments in drugs used for the supportive care of patients receiving chemotherapy, and the availability of affordable generic medicines (Sikora et al., 1999), means that these agents may be relatively safely and economically prescribed and administered in countries from the developing world (Anderson et al., 2008).

Chemotherapeutic drugs are commonly prescribed in combination (Cohen et al., 1996) to patients who are often elderly or have compromised organ function (Mehta et al., 1998).

These agents are inherently toxic causing a number of side effects (Trotti et al., 2003) which affect multiple body systems (Ajani et al., 1990) and even when used appropriately they have the potential to cause life-threatening symptoms leading to hospitalization (Nurgalieva et al., 2009). To counteract these side effects, it is necessary to prescribe supportive therapy which include anti-emetic agents (Hesketh, 2008), bone marrow stimulating agents (Kuderer et al., 2007) and intensive hydration (ASHP, 2002). Furthermore, multiple protocols exist for any one cancer and each mostly contains a combination of drugs with differing doses (Gandhi et al., 2005a), making prescribing in cancer a complex task.

Most chemotherapy prescribing is currently undertaken in the outpatient setting (Calman et al., 1978) and decisions may be based on investigations and laboratory results that have originated outside the hospital (Gandhi et al., 2005a). Dosing of chemotherapy drugs is commonly based on Body Surface Area (BSA) calculations (Mosteller, 1987), although this tradition has been challenged because research has revealed this method's poor correlation with the pharmacokinetics of most chemotherapy drugs (Gurney, 1996). However, BSA calculation continues to be the standard for chemotherapy dosing. In order to produce a prescription with a minimum risk of harm, a number of steps should be followed. These are: correct treatment plan, correct medication dose, order and treatment plan matching, cumulative dose, recalculation of doses, verification of dose calculation and presence of nurse checklist (Kim et al., 2006).

In order to achieve best outcomes, and due to the narrow therapeutic index of these agents, careful tailoring of dosage is necessary to ensure efficacy and reduce the severity of adverse drug reactions (Gurney, 2002). Chemotherapy dosing should therefore be adjusted according to response, toxicities and co-morbidities (Ford et al., 2006).

Given that the writing of a chemotherapy prescription involves a complex set of tasks, the potential for an error is high and likely to cause serious consequences (Boyle et al., 2002). A number of interventions have been recommended to improve prescribing accuracy (Cohen et al., 1996). The first of these recommendations is to ensure that the appropriate number of staff and skill mix is in place and that staff have the relevant knowledge, skills and competencies required to provide cancer care (Pan London, 2011). The provision of cancer care should be guided by SOPs and policies to ensure safe clear instructions are available for staff, who should have access to information pertinent to provision of safe cancer care (Carrington et al., 2010a). Treatment plans should be guided by pre-defined,

evidence-based standardised treatment protocols, which provide guidance on therapies, dosages and scheduling relevant to the treatment (ASHP, 2002). Copies of chemotherapy protocols should be available in doctors' offices, pharmacies and nursing stations to enable prescription verification or double checking (NPSA, 2010b). Prescription verification is a necessary requirement to prevent errors and is usually undertaken by pharmacists (Williamson, 2010) but nurses, other HCWs and even patients have a role (Goldspiel et al., 2000). Patients may also be involved and should be educated about their treatment plans and given clear and simple information leaflets (Carrington et al., 2010a).

Since usually a number of supportive drugs are also prescribed, in addition to the chemotherapeutic agents, the potential of omission errors can be as high as 100% (Huertas Fernandez et al., 2006). Hence, pre-printed prescribing templates were introduced to standardise the prescribing process, improve legibility and provide a guide for doctors through the required details (Cohen et al., 1996). Particulars of chemotherapy prescription templates include: patient demographics, a list of the chemotherapy drugs, with recommended doses according to a pre-defined protocol, supportive agents, the vehicle, route and rate of administration, the sequence of administration and a list of necessary pre-chemotherapy laboratory investigations (Dinning, 2005). Other improvements to the process of prescribing include designing systems to constrain errors (Carrington et al., 2007), improving communication with the patient, drug manufacturers, and among the team as well as introducing an incident reporting system (Cohen et al., 1996).

The effects of these interventions have been shown to reduce medication errors associated with chemotherapy prescribing (Goldspiel et al., 2000). A system improvement project was initiated by the pharmacy department at a large cancer research centre in the US, responsible for provision of 8500 doses every year. The project involved creating a multidisciplinary team to design an incident reporting system, protocol development, computer system improvements, introduction of dose verification, improvement of information access, education and error follow up. The implementation of these changes resulted in a reduction of 23% in prescribing errors and 53% of serious prescribing errors. The evaluation of these system changes involved the analysis of data obtained from the cancer centre's incident reporting system. Incident reporting systems have been recognized to be less robust than other prospective methods in measuring the impact of interventions in reducing chemotherapy associated errors (Bonnabry et al., 2006). However, they are a requirement for patient safety (Kohn, 2000), give an indication of errors and adverse events

associated with chemotherapy (Weingart et al., 2009) and are positively correlated with a more positive safety culture (Hutchinson et al., 2009).

Furthermore, the introduction of CPOE aimed to reduce prescribing errors and ambiguities (NPSA, 2010b). Although there has been scepticism about the use of automation to address errors (Berwick, 2001), CPOE is becoming more widespread than manual prescribing and research has shown improvement with some errors, mainly omission errors and dosing errors (Bonnabry et al., 2006;Kim et al., 2006;Nerich et al., 2010).

However, despite attempts to reduce errors in the chemotherapy process, prescribing errors are common (Fyhr et al., 2012). Evidence from the literature has shown that chemotherapy-related errors can increase healthcare costs (Ranchon et al., 2011), cause serious harm (Soloni et al., 2009), and death (Weingart et al., 2010).

4.3.1 Prescribing errors associated with chemotherapy

Research in medication errors shows little evidence of prescribing errors associated with chemotherapeutic agents (Lewis et al., 2009), for a number of reasons. Most chemotherapy prescribing is currently undertaken in outpatient units of general hospitals, whilst inpatient care is provided in specialist centres (Calman et al., 1978) and data from AE studies have mostly focused on general medicine wards, surgical wards and paediatric wards (Kanjanarat et al., 2003). Some AE studies, however, confirm that cytotoxics can cause AEs and is among the top ten drugs responsible for ADEs (Bates, 1999;Morimoto et al., 2011;Runciman et al., 2003) .

Studies which have focused on chemotherapy-related prescribing errors have shown that they are common and vary from 1.4% (Garzás-Martín de Almagro et al., 2008) to 27.6% (Slama et al., 2005). Older studies were carried out in settings where doctors hand wrote the whole prescription(Alcácera et al., 2001;Díaz-Carrasco et al., 2007). Some of those studies were conducted in hospitals which used standardised pre-printed templates (Ranchon et al., 2011;Garzás-Martín de Almagro et al., 2008) and others used automated systems (Huertas Fernandez et al., 2006;Nerich et al., 2010;Serrano Fabia et al., 2005). Studies employed either prescription review, routinely undertaken by pharmacists and which has become established standard practice in medication error research (Lewis et al., 2009)or retrospective record review. These variations in the methods adopted make direct comparison of their findings difficult. All studies examined the prescribing process with a few identifying ADEs.

Pharmacist review is commonly used in methods studying prescribing errors because it is an established system (Lewis et al., 2009). The role of pharmacists in prescribing error prevention has been repeatedly substantiated (Serrano Fabia et al., 2005). A Spanish hospital introduced pharmacist prescription screening using an automated system where patient details were accessible from the pharmacy (Serrano Fabia et al., 2005). Analysis of prescribing error data over two years revealed that 15.8 errors were detected per 1000 patient days and increased by 41% in the second year.

Pharmacist review was used to study chemotherapy-associated prescribing errors in a French hospital (Slama et al., 2005). Pharmacists used the American Society of Health systems Pharmacists (ASHP) guidelines to review 2826 items prescribed for 285 patients and identified errors in 12.3% of prescribed items. The most common errors involved transfusion method errors (74%), followed by dose errors (8.6%), prescription ambiguities (8.3%) and omission of a necessary medicine (4%). The significance of omission errors associated with handwritten prescriptions was confirmed in another study where they were the second commonest; 21.5% among more than 43,000 prescribed drugs (Díaz-Carrasco et al., 2007).

In comparison, errors of omission, errors in the transfusion method and prescription ambiguities and dose errors were not reported in another study that used CPOE (Huertas Fernandez et al., 2006), where the most common error was missing signature (6.6%) among 30 prescriptions. The use of CPOE does not eliminate other errors entirely. In another study with a comparatively larger sample (14,854) of prescriptions using CPOE, more errors were identified (Nerich et al., 2010). Errors were identified in 1.5% of prescriptions, the most common of which were dose errors (61%). Examples of these errors were when either the wrong drug or wrong numbers were entered into the system (43.1%) and when system alarms such as maximum doses were ignored (16.1%). Other errors included wrong choice of chemotherapy protocol (10.6%) and incorrect scheduling of chemotherapy (12.4%).

There are a number of risk factors associated with prescribing errors. Data collected from pharmacists' prescription screening over a two-year period analysed more than 17,000 chemotherapy prescriptions and found 3.15% contained an error (Ranchon et al., 2012). The risk factors for prescribing errors were a BSA of more than $2m^2$, protocols requiring more than three drugs, protocols containing carboplatin, a requirement for chemotherapy modification, inpatient stay and prescriptions written by resident doctors.

Table 4-3 Studies on Prescribing Errors Associated with Cytotoxic Chemotherapy

Author/year	Setting	Country	Prescribing system	Methods	Sample	Prescribing error rate (% unless otherwise stated)
Alcácera, 2001	IP/OP	Spain	HW	Retrospective record review	4107 prescriptions	6
Serrano-Fabia, 2005	IP/OP	Spain	A	Prescription review	2- year	16.8 IP 1000 pt/days
Slama, 2005	IP/OP	France	HW	Prescription review	6 months-1262	27.6
Huertas Fernandez, 2006	N/S	Spain	HW and A	Controlled trial	30 vs 30	Manual- 100 Automatated-13
Díaz-Carrasco, 2007	IP/OP	Spain	HW	Retrospective record review	43,188 doses	3.1/1,000 preparations
Garzás-Martín de Almagro, 2008	IP/OP	Spain	Mixed	Prescription review	6741 prescriptions	1.4
Nerich, 2010	IP /OP	France	A	Pharmacist review	1 year -14854	3.1
Ranchon, 2011	IP /OP	France	T	Prescription review	2 years-17,150 prescriptions	3.15

IP: Inpatient; OP: Outpatient; A: Automated; HW, Handwritten; T: Pre-printed templates; P: Prescribing. N/R: not reported

The potential for severe harm was reported in the literature and was associated with 16% of prescribing errors (Alcácera et al., 2001). A study that used retrospective methods, analysed prescribing errors (6%) among 250 chemotherapy prescriptions. The authors reported that potentially serious errors were associated with frequently prescribed drugs (etoposide and 5 fluorouracil) and therapeutic agents which were novel at the time of the study (oxaliplatin and topotecan). However, statistical significance associated with these errors was not reported (Alcácera et al., 2001). The severity rate is similar to another study which identified that 21% of prescribing errors have the potential to cause harm (Huertas Fernandez et al., 2006). However, the authors of each study used different severity scales which were not commonly employed in prescribing error research (Lewis et al., 2009).

Published research to date on chemotherapy prescribing errors has shown that they are common and can have the potential for serious consequences. However, the evidence is restricted to western countries and the scale and potential harm of those errors in developing countries, is unknown. Given that chemotherapy use in a developing country (Sudan) is increasing, identifying the scope of prescribing errors is a priority for patient safety.

4.4 Aims and objectives of the study

The aim of this study was to quantify and classify errors associated with chemotherapy prescriptions in a cancer hospital in Sudan and identify contributory factors.

4.4.1 Objectives:

- To determine the systems used to prescribe chemotherapy to patients attending a Sudanese cancer hospital
- To identify medication errors made during the prescribing of chemotherapy
- To classify detected prescribing errors
- To analyse the potential causes of prescribing errors

4.5 Study Design and Methods

This study used a mixed research method to explore the types and potential causes of prescribing errors associated with chemotherapy. The purpose of the mixed method design

was to both quantify and characterise the types of errors and also gain a perspective of doctors' experiences when errors occur and their views about the cause of these errors.

The study was undertaken during February and March of 2011 in a major cancer centre Khartoum, which delivers care to 7000-8000 cancer patients each year (Abuidris, 2009;Ahmed et al., 2013), of which approximately 100 outpatients/day are treated at the chemotherapy day unit. Patients diagnosed with cancer from across Sudan are referred by their doctors to the outpatient cancer department. At the time of the study, the outpatient department held 9 clinics run by 42 medical doctors organized into consultant teams, each comprising one senior consultant, junior consultants, senior registrars, junior registrars and medical officers.

Study design followed four interlinked stages, described in Figure 4-2.

Stage One- An exploratory study using key informant interviews was conducted to describe the workflow in the outpatient clinic and map the processes followed when writing a prescription for chemotherapy. Findings from this stage were used together with information obtained in the literature to inform the development of a data collection tool used in stage two.

Stage Two- An observation study of pharmacists' prescription screening was used to identify prescribing errors in prescriptions presented to the pharmacy department. Incidents identified in this stage were used in stage three.

Stage Three – A qualitative study using the Critical Incident Technique (CIT), to discuss errors identified in Stage Two. This study aimed to explore the contributory causes of prescribing errors associated with chemotherapy prescriptions.

Stage Four- Focus group interviews were conducted with doctors who were not available for CIT interviews but were involved in errors to explore their opinions and experiences regarding the nature and causes of prescribing errors associated with chemotherapy.

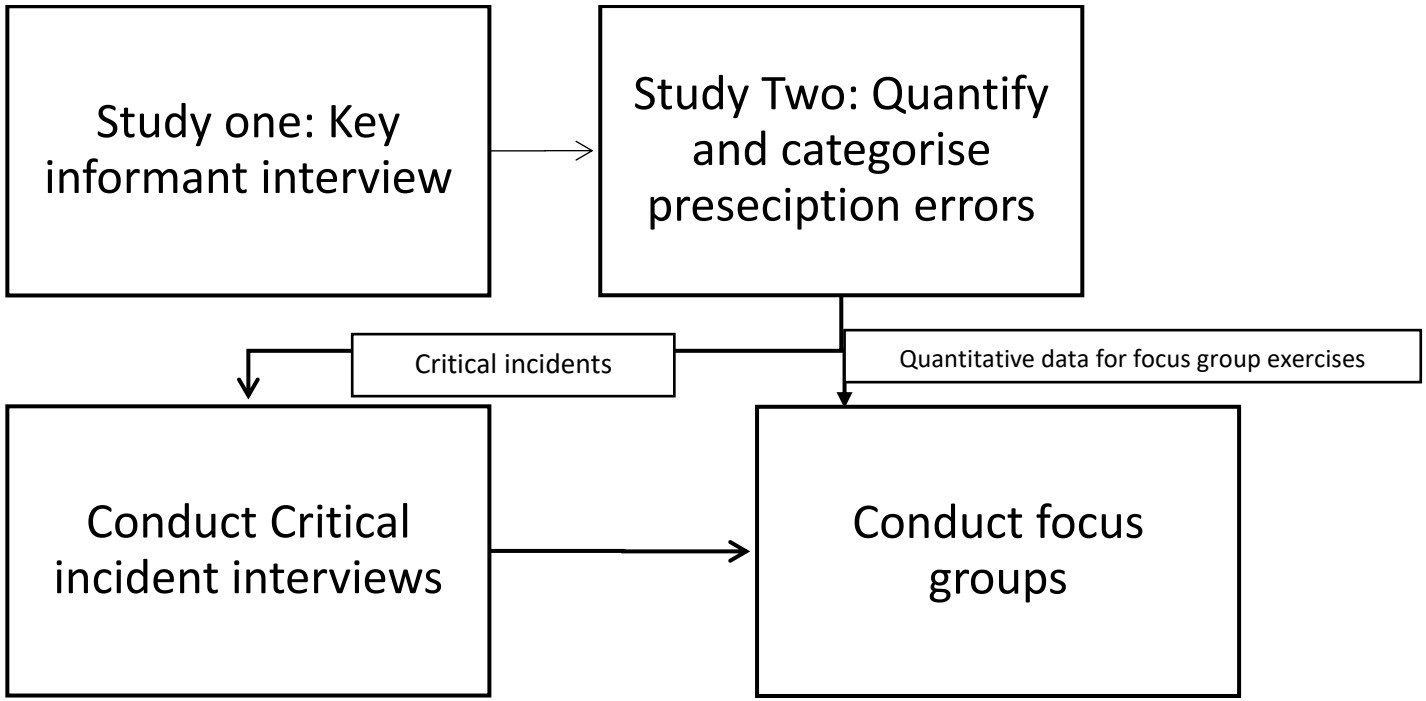


Figure 4-2 Summary of prescribing error methods

4.6 Stage one: Mapping the prescribing process using Key informant interviews

The aim of this stage of the study was to obtain a description of the outpatient clinic and map the prescribing process. This was necessary because during researching patient safety culture (Chapter 3), it became evident that written standard operating procedures were not routinely used and nurses, doctors and pharmacists were guided in their tasks by observing their peers. Key informant interviews were used to establish a description of how the outpatient clinics were run and what processes were used to prescribe chemotherapy.

4.6.1 Key informant interviews

Spradley (1979) describes key informant interviews as in-depth ethnographic interviews that use informants who are particularly knowledgeable about a certain field. Ethnographic techniques are well suited to probing human behaviours and culture and understanding the causes of sensitive issues (Dixon-Woods, 2003), which makes this technique suitable to exploring the undocumented processes followed in chemotherapy prescribing.

Interviews follow a flexible schedule that allow the interviewee to deviate and put forward new ideas and concepts. They have the advantage of offering the individual a feeling of being valued because their opinions are being sought as well as obtaining quality information. However, there are limitation using this technique because such interviews are neither generalizable nor representative and are time consuming to carry out and often difficult to analyze (Bowling, 2002;Spradley, 1979).

4.6.2 Sampling and sampling technique

In order to obtain a rich and varied description of the prescribing process, key informant interviews were conducted with a number of doctors. Since medical officers were not authorised to prescribe cytotoxic chemotherapy, they were excluded from this study.

Unlike quantitative research methods where a large sample is recruited, qualitative research does not seek to generalize findings and hence a smaller number of participants is adequate (Smith, 2002;Patton, 1990). In qualitative research the common sampling techniques used are convenience sampling, purposive sampling, snowballing and theoretical sampling (Bowling, 2002). Purposive sampling method was used because the views of experienced doctors were important to provide valuable input into describing work

practices during the prescribing process. Purposive sampling has been used in qualitative medication error research (Evans et al., 2006;Hand et al., 2000;Sanghera et al., 2007;Franklin et al., 2011;Ghaleb et al., 2005) where they targeted "information rich" individuals.

Purposive sampling was used to identify a doctor from different grades; senior consultant, junior consultant, senior registrar, junior registrar. Doctors from each grade, with the longest experience at the cancer hospital, were approached and those that consented were entered into the study. Four doctors were included in these interviews and each doctor was given a PIL (Appendix 4-1) and consent form (Appendix 4-2), 48 hours before the interview date. Once the doctors agreed and consented to the interview, a date and time was scheduled.

4.6.3 Development of the Interview Schedule

The interview schedule was developed using the principles outlined by Spradley (1979), using grand tour and mini tour questions. Prior to administration of the interview schedule, the content and wording were repeatedly reviewed by the supervisory team and changes were made to remove ambiguity and irrelevant questions. The interview schedule is attached separately in Appendix 4-3. Interviews were designed to last between 30-45 minutes to avoid interview fatigue and minimize the impact on service delivery. Prompts were used throughout the interview to encourage the interviewee to increase the richness and depth of the information provided and to support dialogue between participant and researcher.

4.6.4 Data Collection

After obtaining consent, the researcher briefed the interviewee using the pre-agreed criteria, outlined in Appendix 4-3. Interview participants were made aware that they could withdraw at any time during the interview process. The interviews were held in a quiet location specified by the interviewees and, after obtaining permission, the interviews were recorded using a digital audio recorder (Sony ICD-BX800 voice recorder).

The interviews were conducted using a mix of English and Arabic languages, with the introduction, questions and prompts being entirely in English. Participants were given the freedom to answer in either English or Arabic language. These types of discussions are

common in Sudanese culture where dialogues use a mix of both languages during the conversation and more so when using scientific terminology e.g. disease names, patient condition and medicines names which are spoken in English.

4.6.5 Data management and Analysis

Recorded interviews were listened to several times before transcription was undertaken. Interviews were transcribed *verbatim* by hand and later the Arabic content was translated into English for the purposes of analysis using the process outlined in Chapter 2 of the current thesis.

Transcribed interviews were entered into NVIVO; a qualitative analysis software system for storage and coding. Framework Analysis, as described by Richie and Spencer (1980), was used for analysis of the results.

For this study, text was coded using Framework analysis (described in Chapter 3 section 3.6.7) to major emerging themes that described the prescription process. The framework adopted was the British Oncology Pharmacy Association (BOPA) Standards for Clinical Pharmacy Verification for Cancer Medicines (Table 4-4). This framework was used for categorizing interview data concerning the prescribing process.

Table 4-4 Prescription Accuracy Guidelines (adapted from BOPA 2010)

Prescription Category
1. Accurate patient details (age, height and weight) are correct on prescription 2. Appropriate prescriber's details and signature 3. Regimen is appropriate for patient's diagnosis, medical history, performance status and chemotherapy history according to protocols approved by RICK drugs and therapeutic committee 4. Regimen is the intended treatment as documented in the clinical notes 5. Timing of administration is appropriate 6. There are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s) 7. Body surface area (BSA) is correctly calculated, taking into account recent weight 8. All dose calculations and dose units are correct and have been calculated correctly according to the protocol 9. The patient has not exceeded the cumulative dose, if appropriate according to manufacturer's recommendations 10. Where the dose was altered from the last prescription, check reason for any dose reduction(s) 11. Check method of administration is appropriate 12. The patient's laboratory values, FBC, U&E's and LFT's are within accepted limits if appropriate. 13. The doses of prescribed chemotherapy drugs are appropriate with respect to renal and hepatic function and any experienced toxicities 14. All other essential tests have been undertaken 15. The prescription contains appropriate supportive care is that is compatible with the patient

4.6.6 Results of the Key informant interviews

Four key informant interviews were conducted with a doctor from each prescriber grade. Doctors described clinic organization and the prescribing process. They explained their role in prescribing and the pharmacy role in transcribing of prescriptions onto administration sheets which were subsequently used by nursing staff to guide them in the administration of chemotherapy.

Doctors were consistent in description of clinic organization; however, a number of inconsistencies were noted with regards to the prescribing process. Each doctor appeared to follow a different process in writing a prescription. The sum of the processes followed by the key informants are provided and outlined in Table 4-5.

Doctors provided details on clinic organization and explained that all teams ran two clinics every week, the 'Referral clinic' and the 'New patient's clinic'.

All new patients present at the 'New Patients' clinic', where they were given a patient record number and patient medical file. Once the patient receives the file, they present to a consultant clinic. Consultants always carried out the initial consultation for patients. This involved; taking a medical history, patient clinical examination, assessment of investigations and preparation of a provisional treatment plan. On completion of the initial consultation, patients who do not require emergency treatment are given an appointment to attend the referral clinic. The interim period gave doctors the opportunity to discuss new cases at weekly clinical meetings, where a final decision is made with regards to the treatment plan.

According to the treatment plan, patients may be scheduled to either receive chemotherapy, radiotherapy or a combination of both, given as a course of pulsed therapy separated by specified time intervals, as detailed in the treatment protocol.

When doctors wanted to issue a prescription for chemotherapy, they used a number of indicators to assess whether or not the patient was fit for chemotherapy. The first of those was to conduct a performance scoring based on the Eastern Cooperative Oncology Group (ECOG), which guides doctors in assessing the patient's level of functioning (Oken et al., 1982). The second step involved carrying out a patient medical and drug history to take into consideration drugs which may interact with chemotherapy, other contraindications and past doses of chemotherapy if applicable. The second step would be to assess the patient's laboratory investigations, which may include full blood count, liver function tests and renal function. The fourth step comprised of the actual writing of the prescription which was

guided by the treatment plan detailed in the patient's medical file. The chemotherapy dosing was decided using the patient's BSA, renal function or liver function as applicable. The final step involved completing the prescription form with the following details: patient name, diagnosis, gender, chemotherapy drug and doses, signature of prescribing doctor and date. Once the doctor completes the prescription, it is handed to the patient, along with the medical notes and the patient is instructed to take the documentation to the pharmacy, in order to obtain an appointment for chemotherapy.

Table 4-5 Themes Emerging from Key Informant Interviews

Dimension of interview	Theme emerging from interview
Clinic Organization	• Teams ran two clinics every week, the 'Referral clinic' and the 'New patients' clinic'. <u>New patients</u> • New patients present at the "new patient clinic" • Patients are allocated a patient number and a patient medical file. • On receipt of patient number and medical file, patients returned to the clinic where they were examined by the consultant and their investigations reviewed. • A decision is made according to the clinical status of the patient to either be admitted (oncologic emergency), receive chemotherapy, receive radiotherapy or referred to another hospital <u>Follow up patients</u> • Patients are followed up in the "referral clinic" • Patients present for subsequent cycles for chemotherapy • Investigations carried out include, performance, score, tumor assessment, blood parameter investigation and others according to the chemotherapy required
Prescribing Process	• Assess patient performance score • Study clinical investigations to decide course of therapy • Assess patient history to ensure no contraindications, drug interactions, chemotherapy interval and cumulative doses • Decide on chemotherapy protocol to be given • Calculate BSA or Creatinine clearance to decide doses • Fill prescription form by free hand: patient name, diagnosis, gender, chemotherapy, doses, signature • Patient presents at pharmacy with documentation where prescription details are transcribed onto an administration sheet that contained the supportive drugs, infusion fluids, route of administration, rate of administration and sequence of drug administration
Training for prescribing Errors	• General training in oncology and chemotherapy protocols • No specific training for prescribing • Dose errors • Calculation skills, busy clinics, poor access to information, disorganized clinic.

On presentation at the pharmacy department, pharmacists studied the notes and screened the prescription for accuracy. Once the pharmacist was satisfied with the prescription, it would be transcribed onto a protocol specific chemotherapy administration form. The form contained standard protocol specific supportive medication and was used by nurses to aid in the administration of chemotherapy on the ward. Finally, the patient would be given an appointment to receive chemotherapy.

4.7 Stage Two- Identification of prescribing errors

Pharmacists identified chemotherapy prescribing errors during their routine pharmacy practice, which were recorded onto a data collection tool which was developed to record particulars of these errors. Previous work had revealed the potential limitations of using pharmacist prescription screening to detect errors (Franklin et al., 2009). Firstly, during routine practice, pharmacists may consider some errors minor and not worth reporting. Secondly, prescription screening rigour can be affected by individual pharmacist expertise and clinical knowledge. Finally, pharmacists in their daily practice have less time than a dedicated researcher to study the medical records and identify errors. In order to reduce the impact of these limitations, two measures were undertaken. Firstly, pharmacists responsible for screening chemotherapy orders were trained to ensure consistency of prescription screening and secondly, an independent data collector observed and recorded those errors onto the data collection tool. The second measure was introduced to eliminate the burden of data recording among the pharmacy team and ensure accurate data collection.

4.7.1 Research team

After obtaining approval from the chief pharmacist at the cancer centre, the research team consisted of the following: the principal researcher, three clinical pharmacists who were responsible for screening the prescriptions and transcribing prescription details onto the appropriate pre-printed chemotherapy administration templates, and a data collector who was responsible for recording of prescription details and prescribing errors.

4.7.1.1 Research Team training

The data collector and pharmacists were trained in patient safety research and screening of chemotherapy prescriptions. In addition, the data collector was provided with an

orientation to the outpatient chemotherapy clinic and instructed in completion of the prescribing error tool. A description of the training provided in presented in Table 4-6.

Table 4-6 Research team training

Training Parameter	Description
Patient safety research	• Introduction to the principles of medication safety research using a training package prepared by the WHO (2010). • Training package provided a video that detailed the RCA of an inadvertent error and a booklet on patient safety (WHO, 2008a). Video contained a description of patient safety research and findings to date.
Standardisation of prescription checking process	• Pharmacists completed the pharmacy department training programme for chemotherapy prescription checking. • A prescription checking exercise was evaluated using BOPA Standards for Clinical Pharmacy Verification of Prescriptions of Cancer Medicines (BOPA, 2010).
Training in data collection	• The data collector was trained in retrieving information from the patient files and prescription and recording the data onto the collection tools.
Outpatient clinic orientation	• Shadowing a clinic based clinical pharmacist for a week to observe the organization of the outpatient clinic. • Training in reading medical records.

4.7.2 Development of the data collection tools

To record all prescriptions presented at the pharmacy, two separate data collection tools were designed; one for collecting routine data on each prescription presented and one for recording details of identified errors.

The prescription particulars data collection tool was designed to collect data for 14 prescriptions per sheet for ease of recording (Appendix 4-4). The tool consisted of prescriber particulars, patient details, chemotherapy particulars and clinic details (Table 4-7).

The prescribing error collection tool (Appendix 4-5) was developed from the steps identified from stage one of the study and BOPA (2010) guidelines for verification of prescriptions for cancer medicines (Table 4-8). The tool was comprised of three elements; governance, documentation and clinical accuracy verification of prescriptions.

Table 4-7 Prescription data collection tool

Parameter	Details
Patient details	Hospital number, Gender
Prescriber details	Consultant team, grade of prescriber
Chemotherapy order details	Diagnosis, Drugs prescribed, Chemotherapy protocol
Clinic details	Clinic location (RICK/ private clinic), Day of clinic
Error Details	Presence or absence of error, Error Number

4.7.3 Pilot study

After training, the data collector was asked to pilot the data collection tool by recording prescriptions received in the pharmacy and to record error details. The objectives of the pilot were to test, refine and validate the data collection tools. Piloting of quantitative research tools requires a sample of 50-100, of which the lower limit (50) was used in a validation of a scale for scoring the severity of medication errors (Dean and Barber, 1999).

The pharmacy department screen and process 80-100 prescriptions for patients receiving chemotherapy in the day unit, daily. After discussion with the research team, a decision was made to conduct the pilot that on a sample of one day's work or until there were no more alterations to be made to the tool. After completion of the pilot study, a number of alterations were made to the original data collection tool (Table 4-9).

Table 4-8 Components of prescribing error checklist based on Standards for Clinical Pharmacy Verification of Cancer Medicines (Adapted from BOPA guidelines 2010)

Parameter	**Standards for prescription verification**
Governance	• Prescriber is authorized to prescribe chemotherapy
	• Protocol is according to local approved protocols
Documentation	• Treatment plan is documented in the patient record
	• Protocol is as intended in the treatment plan
	• Patient demographics have been recorded
	• Prescription details are complete
	• Pharmacist to sign that prescription is authorized for dispensing
Clinical accuracy verification of prescription	• Protocol is appropriate to diagnosis
	• No known drug interactions or allergies
	• Timing of administration is appropriate
	• Body surface area has been correctly calculated as appropriate
	• Dose calculations are according to protocol or other relevant clinical findings
	• Cumulative dose as appropriate
	• Methods of administration are appropriate
	• The necessary laboratory values and clinical investigations are within agreed limits according to protocol
	• Doses are appropriate to renal and hepatic function
	• The necessary supportive care medicines have been prescribed.

Table 4-9 Changes to the prescribing error tool after piloting

Element of prescribing error tool	Changes after piloting
Choice of drug	• Added a section for not according to approved protocols • Substituted protocol not according to histopathology with protocol not appropriate with diagnosis • Removed the detailed section with supportive medicines. Prescriptions are transcribed into a pre-printed template (administration sheet) containing necessary supportive care medicines including infusions, antiemetics and others
Drug/protocol contraindications	Divided the section to assess if the patient is fit for chemotherapy into: physical fitness, laboratory data and organ function
Dose error	Added wrong dose unit
Prescription particulars	Added a section to assess the legibility and completeness of the prescription

4.7.4 Consent of doctors and prescribers

A ten-minute talk about the study was given to the doctors during the weekly clinical meeting before the start of data collection about the study. The talk included the following: general aims and objectives of the project, data collection period, prescription details and errors to be collected, maintaining confidentially and anonymity of prescribers; doctors involved in errors were invited to take part in a 45-60-minute interview.

4.7.5 Data collection

The data collector was situated in the pharmacy department to collect data on prescriptions screened by the clinical pharmacists. Data collection was divided into two sections:

1. Prescription and patient details - the information was retrieved by reviewing patient records and prescriptions, presenting to pharmacy. Details were recorded onto the prescription data collection tool (Appendix 4-4).
2. Prescribing error details- once an error was identified, it was recorded on the prescribing error collection tool and given a unique serial number to identify the prescription from the prescription records (Appendix 4-5).

Each of the prescriptions and patient medical records presented to the pharmacy, during the data collection period were included in the study. These prescriptions were for adult patients receiving chemotherapy treatment on the day ward. Prescriptions returned to prescribers because missing information or details were not included because it was not possible to ensure they were retrieved.

The data collection period and the number of medication orders reviewed was guided by previous medication safety research, practice at RICK and research burden. Previous medication safety research in cancer chemotherapy involved the screening of 1262 chemotherapy prescriptions (Slama et al., 2005) and 22,216 chemotherapy orders (Markert, 2009) over 6 and 24 months consecutively. In the study setting, preliminary data collected in 2009, identified that pharmacy at RICK processed approximately 4000 chemotherapy orders each month, of which almost half were outpatients. Therefore, a decision was made to collect data from 2000 prescriptions over one month. This decision was based on typical sample size, workflow, exclusion of paediatric prescriptions, inpatients and to reduce the burden on the observer. All errors for each prescription were recorded on individual prescription data collection forms.

4.7.6 Data management and analysis

Prescribing errors data were validated, categorised and potential severity assigned before data entry and analysis.

4.7.6.1 Error validation and categorisation

Validation was carried out in two steps: the first being error validation within the research team and the second was obtained by an independent review from a senior oncology consultant.

Step One- Validation by research team

During regular intervals of the data collection period, the research team met to discuss and categorise the errors. Categories of prescribing error were based on previous medication safety research (Franklin et al., 2011) and modified according to the BOPA screening of prescriptions (see Table 4-10).

Step two- Validation by consultant review

After categorisation, the errors were independently reviewed by a consultant oncologist. Disagreements between the research team's decision and the consultant view were resolved in a meeting where it was decided that 7 prescriptions with errors should be excluded from the analysis. The prescriptions were excluded because it was inferred that the prescribing decision was based on specific clinical reasoning. An example was a prescription for CHOP chemotherapy in a patient who had less than desired haemoglobin level. In this scenario, the consultant explained that the treating doctor would proceed with treatment because treating the underlying malignancies is expected to allow the haemoglobin to rise to normal levels.

4.7.6.2 Determining potential error severity

In order to assess the clinical significance of the errors, the potential severity of errors can be assessed using a validated severity tool. A number of tools have been developed but only two of these tools have been found to be valid and reliable for use in assessment of error severity. Both the NCC MERP (National Coordinating Council for Medication Error Reporting and Prevention) and a severity tool developed by Dean and colleagues (1999) have published reliability and validity results (Garfield et al., 2013). The tool developed by Dean and colleagues required a 4-5-member panel to assign error severity (Dean et al., 1999), whereas the NCC MERP tool requires one person to be involved in assigning error severity. The NCC MERP tool was developed in the USA for categorisation of medical errors and includes nine categories of error based on severity and patient outcomes (Figure 4-3). The NCC MERP developed an algorithm to enhance interpreter consistency in assigning error categories and reduce variability (National Coordinating Council on Medication Error Reporting and Prevention, 2012). The tool has been validated for use in research settings (Bobb et al., 2004;Forrey et al., 2007;Garfield et al., 2013).

The severity rating was based on the potential of the prescribing error to result in an ADE or loss of therapeutic response, if it had not been intercepted.

Table 4-10 Categories of prescribing errors

Category	Description
Schedule	1. Continuation of drug for a longer duration than necessary e.g. extra cycle prescribed 2. Prescribing a protocol for inaccurate length of therapy 3. No indication for drug prescribed 4. Duplication of therapy/ prescribing therapy with increased frequency 5. Total cycle correct but divided into days incorrectly /Unintentional missing of a cycle
Drug contraindicated	1. Prescription of drug to which patient has significant allergy 2. Prescription of drug to which patient has clinical contra-indication such as low haematology parameters, renal failure or liver impairment 3. Continuing a drug in the event of a clinically significant ADR 4. Prescription of drug that is contra-indicated due to drug interaction 5. Prescription of anthracyclines in a patient who has an ejection fraction less than 30%. 6. Prescription of chemotherapy when neutrophil count $<1.5x10^{6/}$/ml or haemoglobin <6g/dl or platelets $<150x10^{6}$/ml 7. Prescription of chemotherapy when ECOG performance score is>2 (Oken et al., 1982) 8. Prescription of a taxane when liver function tests: bilirubin 5x upper limit of normal or liver transaminase level >10x upper limit of normal 9. Prescription of cisplatin when renal function in below 30ml/min
Choice of drug	1. Prescription of a protocol/ drug that was not intended 2. Prescription of a protocol that is not recommended for management of the specific
Wrong dose	1. Exceeding the maximum cumulative lifetime dosage for anthracylines and similar drugs 2. Dose/rate mismatch for infusions 3. Overdose/underdose by more than 5% due to inaccurate calculation of Body Surface Area. 4. Overdose/underdose by more than 5% due to inaccurate application of Calvert equation for carboplatin 5. Overdose by more than 5% due to low renal function or increased liver test 6. Choosing a dose more/less than 5% of that specified by the chemotherapy protocol 7. Wrong dose calculation according to renal and liver function
Administration of drug	Wrong route, formulation, Administration times, Instructions for IV administration, Start date or days of chemotherapy
Prescription details	Missing Product or formulation, Strength or dose, Route, signature, patient name, date, inaccurate spelling or abbreviations

Severity was assigned using a two-step process.

1. The principal researcher and the clinical pharmacists involved in the study reviewed all the prescribing errors made a prediction of potential outcome of errors and assigned severity rating using the NCC MERP algorithm (Figure 4-3). The potential clinical outcomes were determined according to the side effect profile of the drugs using the Electronic Medicines Compendium as a reference resource.
2. To ensure validity, and that potential outcomes and severity rating were carried out within the appropriate clinical context, the results were reviewed by the senior consultant who participated in error validation. Discussions took place to reach an agreement on contentious predictions.

Once agreement was reached, error category, and severity were recorded onto the prescribing error collection tool.

4.7.6.3 Data entry and analysis

Data from completed prescription and error data collection tools was coded and entered into the SPPS® Version 22 for data management and analysis. Data coding and entry was checked independently by a member of the research team for one in every 10 prescriptions. Descriptive statistics was used to produce frequency tables of patient gender, disease characteristics, number of cytotoxic chemotherapy agents prescribed and chemotherapy protocols. Associations between chemotherapy protocol and error categories were explored using chi-squared analysis. In addition, associations between individual drugs and error were explored using chi-square tests. Drugs involved in error were computed separately to identify if there was a statistically significant association between drug and occurrence of an error. A chi-squared value of <0.05 was considered to be a statistically significant result.

Multivariate regression analysis was conducted to explore the effect of prescriber grade, number of drugs within a protocol and day of administration on the likelihood of an error occurring. An adjusted Odds Ratio (OR) of more than 1 was regarded as having a statistically significant impact on errors, as long as the confidence intervals do not cross the line of no effect.

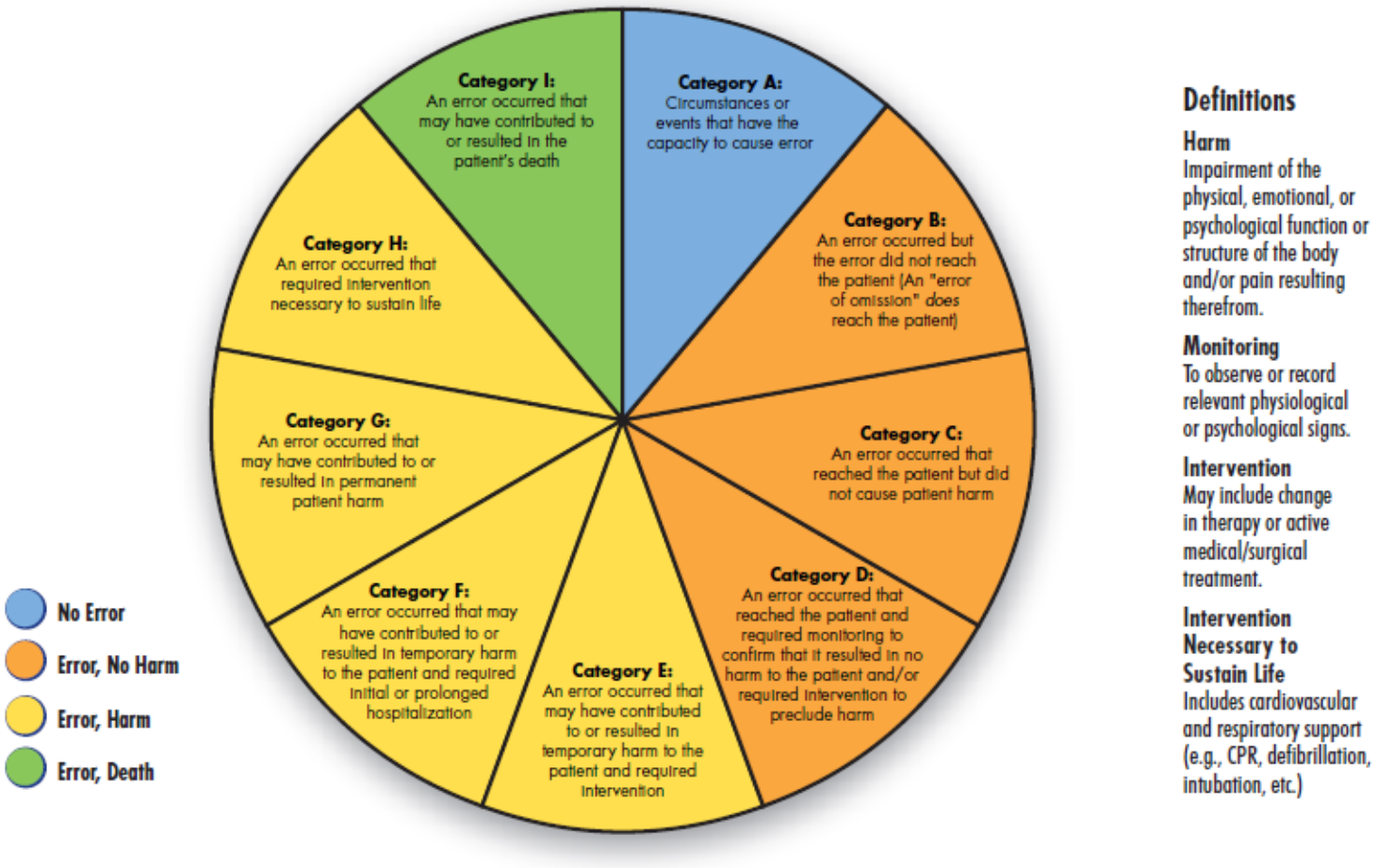


Figure 4-3 NCC MERP Index for Categorizing Medication Errors (obtained from http://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf)

4.7.7 Results

4.7.7.1 Patient characteristics

A total of 2194 patients presented with prescriptions for chemotherapy (see Table 4-11). The majority of patients were female (71%) and presented with breast cancer (36.5%) and most (82.5%) required prescriptions for combination chemotherapy containing between two and four drugs.

Table 4-11 Table of patient characteristics

Characteristic	Total (%)	Female gender n (% of total)
Diagnosis		
Breast	837 (38.1)	801 (96)
Gynaecologic	426 (19.4)	426 (100)
Gastrointestinal	251 (11.4)	95 (38)
Haematological malignancy	237 (10.8)	72 (30)
Head and Neck	218 (9.9)	63 (29)
Sarcoma	108 (4.9)	48 (44)
Lung cancer	67 (3.1)	12 (18)
Urological (Prostate)	30 (1.4)	-
Others	20 (0.9)	10 (50)
Total	**2194**	**1557 (71)**
Number of drugs per protocol		
One drug	383 (17.5)	257 (70)
Two drugs	1038 (47.3)	713 (69)
Three drugs	720 (32.8)	538 (74)
Four drugs	53 (2.4)	19 (36)

4.7.7.2 Chemotherapy distribution according to primary diagnosis

Most patients presented with prescriptions for anthracycline based chemotherapy (16.7%) for breast cancer. This was followed by single agent chemotherapy (16.4%) and then cisplatin combination therapy (15.8%) which were used to manage a range of different cancers (see Table 4-12).

Table 4-12 Chemotherapy protocol and diagnosis distribution of prescriptions

Chemotherapy protocol*	Breast	Gynae	Gastro	Haem	H&N	Urological	Lung	Sarcoma	Others	Total (%)
Anthracycline based therapy	366	-	-	-	-	-	-	-	-	366 (16.7)
Single agent	146	70	74	2	30	17	7	12	1	359 (16.4)
Cisplatin combination	-	41	103	-	145	9	21	25	2	346 (15.8)
Taxane platinum doublet	-	251	11	1	-	-	22	-	3	288 (13.1)
Non-approved protocol	72	54	24	27	35	4	3	36	14	269 (12.3)
Taxane based therapy	214	-	-	-	-	-	-	-	-	214 (9.8)
Lymphoma Protocol (CHOP &ABVD)	-	-	-	208	-	-	-	-	-	208 (9.5)
CMF	39	-	-	-	-	-	-	-	-	39 (1.8)
Ifosfamide combination	-	-	-	-	-	-	-	35	-	35 (1.6)
Fluoropyrimidine based therapy	-	-	31	-	-	-	-	-	-	31 (1.4)
Platinum doublet	-	3	4	-	8	-	13	-	-	28 (1.3)
Gemcitabine combination	-	-	4	-	-	-	-	-	-	4 (0.2)
Others	-	7	-	-	-	-	-	-	-	7 (0.3)
Total	**837**	**426**	**251**	**237**	**218**	**108**	**67**	**30**	**20**	**2194**

For details of chemotherapy protocols- see Appendix I

Abbreviations: Gynae= gynaecological cancer, gasrto= gastrointestinal, H&N= head and neck cancers

4.7.7.3 Error frequency and category

Of the 2194 prescriptions written, a total of 314 errors were identified in 219 (10%) prescriptions. Of these, a total of 145 (66.2%) prescriptions, contained one error, 53 (24.2%) contained two errors and 21 (9.6%) contained three errors, so that approximately one third of those prescriptions with errors contained more than one error. This was largely due to the prescribing of combination regimens. For example, the inaccurate calculation of the BSA of a patient prescribed a 3-drug combination chemotherapy protocol, means that three errors were recorded on the prescription.

Dose errors were the most commonly identified (34.1%) and formulation errors were the least common, where only error was identified (see Table 4-13). Nearly one quarter of the errors identified were seen in prescriptions for a cisplatin based protocol (22.6%) and errors were more likely for prescription containing either cisplatin ($p < 0.001$, chi-sqaure test) or carboplatin ($p = 0.019$, chi square test) prescriptions.

A more detailed analysis of dose errors (see Table 4-14) showed that there were almost equal number of both overdoses (53; 49.5%) and under-doses (54; 50.5%). However, calculation errors (86; 74%) were the most common. More than a quarter (30; 28.0%) of dose errors were due to miscalculation of BSA, mostly resulting in under-dosing (28; 26.2). Other dose errors were caused by inaccurate calculation using the Calvert equation (25; 23.4%) and inaccurate dose adjustment according to renal function tests (RFTs) (23; 21.5%).

In more than one quarter of prescriptions with errors, the chemotherapy prescribed was contraindicated (87; 27.7%). More than half (50; 57%) were written when a blood parameter was well below the minimum desired limits (see Table 4-9 for limits) specified for the patient to receive chemotherapy (see Table 4-15). Around one fifth of prescriptions with errors (18; 20.7%) were written for patients with impaired renal function. In contrast, only a minority of prescriptions (2.3%) were written for patients with severely impaired liver function.

Table 4-13 Error categories in each chemotherapy protocol group

Protocol	No. of prescriptions	Error Category								Total error (%)
		Dose	Drug contra-indicated	Schedule	Choice of protocol	Length of therapy	Prescription details	Omission error	Formulation	
Anthracycline based therapy	366	18	14	5	5	2	4	2	-	50 (15.9)
Cisplatin combination	346	24	17	8	-	16	5	1	-	71(22.6)
Single agent	359	11	12	3	4	3	8	2	1	44(14.0)
Taxane platinum doublet	288	22	7	5	3	-	1	-	-	38(12.1)
Non-approved protocol	269	9	19	1	-	8	6	2	-	45(14.3)
Taxane based therapy	214	8	7	2	-	-	5	1	-	23(7.3)
Lymphoma Protocol	208	11	4	9	1	-	-	1	-	26(8.3)
CMF	39	3	-	-	-	-	-	-	-	3 (1.0)
Ifosfamide combination	35	-	-	-	-	-	-	2	-	2(0.6)
Fluoropyrimidine based therapy	31	1	2	1	-	1	-	-	-	5(1.6)
Platinum doublet	28	-	5	1	-	1	-	-	-	7(2.2)
Gemcitabine combination	4	-	-	-	-	-	-	-	-	-
Other	7	-	-	-	-	-	-	-	-	-
Total (%)	**2194**	**107(34.1)**	**87 (27.7)**	**35 (11.1)**	**13(4.1)**	**31 (9.9)**	**29(9.2)**	**11(3.5)**	**1(0.3)**	**314**

Table 4-14 Characteristics of dose errors

Dose errors	Underdose (%)	Overdose (%)	Total (%)
Inaccurate dose calculation using BSA	28 (26.2)	2 (1.9)	**30 (28.0)**
Inaccurate dose using Calvert equation*	13 (12.1)	12 (11.2)	**25 (23.4)**
Inaccurate dose adjustment according to RFT	1 (0.9)	23 (21.5)	**24 (22.4)**
Dose transcription error	11 (10.3)	8 (7.5)	**19 (17.8)**
Inaccurate dose adjustment according to LFTs	-	2 (1.9)	**2 (1.9)**
Other	1 (0.9)	6 (5.6)	**7 (6.5)**
Total	**54 (50.5)**	**53 (49.5)**	**107**

****Calvert equation is used to calculate doses of carboplatin in terms of targeted area under the curve (AUC) and glomerular filtration rate (GFR). Dose of carboplatin = AUC (FGR +25) (Kaestner et al., 2007a) Abbreviations: BSA: Body Surface Area, LFTs: Liver function tests, RFTs: Renal Function Tests***

Table 4-15 Characteristics of drugs contraindicated

Reason for drug contraindication	Frequency (%)
Depleted blood count*	50 (57.4)
Impaired renal function (Creatinine clearance <30mL/min)	18 (20.7)
Patient ECOG performance score >2**	6 (6.9)
Cardiac Ejection fraction <30% for anthracycline	5 (5.7)
Raised White cell > $12x10^6$/mL	4 (4.6)
Impaired Liver function ***	2 (2.3)
Cumulative lifetime dose of anthracycline reached (>450mg/m^2)	2 (2.3)
Total	**87**

****neutrophil count <$1.5x10^6$/mL, haemoglobin <6g/dL, platelets <$150x10^6$/mL, **ECOG performance score:0-5 (Oken et al., 1982), ***Impaired liver function: bilirubin 5x upper limit of normal , liver transaminase level >10x upper limit of normal***

4.7.7.4 Potential predictors of prescribing errors

Although most prescriptions (34%) were written by senior registrars, all grades of prescriber were involved in errors (see Table 4-16). The highest rate of errors (20%) was identified among the group least involved in prescribing; unauthorised prescribers, followed by junior registrars (12.8%). Interestingly, senior registrars responsible for most of the prescriptions made the least number of errors (8.4%). The majority of errors (88%) had the potential to cause either serious/significant harm (n=171, 78%) or life-threatening harm (n=21, 10%).

Table 4-16 Prescriber grade and potential severity of errors

Prescriber grade	**Prescription workload (%)**	**Potential severity**			**Total (% error from total prescribed)**
		Low capacity for harm	Serious/ significant	Life-threatening	
Senior registrar	746 (34.0)	7	51	5	63(8.4)
Junior consultant	589 (26.8)	9	51	6	66(11.2)
Senior consultant	587 (26.8)	9	39	6	55(9.4)
Junior registrar	257 (11.7)	2	27	4	33(12.8)
U/A*	15 (0.7)	-	3	-	3(20.0)
Total (%)	**2194**	**27 (12.3)**	**171 (78.1)**	**21(9.6)**	**219**

U/A unauthorised prescribers

Multivariate regression was used to examine the potential impact of prescriber grade on the likelihood of a prescribing error and its severity. After controlling for prescriber grade and severity of errors, there were no statistically significant differences for likelihood of error and severity of error (Table 4-17). The multivariate model indicated that although differences existed between all grades of prescriber in comparison to senior consultants, however, these were not statistically significant. Junior registrars (adjusted OR 1.43, 95% CI 0.9-2.26) were 43% more likely to be involved in an error when compared with consultants. Senior registrars (adjusted OR 0.88, 95% CI 0.60-1.29) were 12% more likely to be involved in an error and junior consultants (adjusted OR 1.23 ,95% CI 0.84-1.78) were 23% more likely to be involved in an error when compared to senior consultants. Furthermore, junior registrars were more than twice likely to be involved in an error with a potentially moderate

severe outcome (adjusted OR 2.25, 95% CI 0.57-8.94) or an error with a potentially severe/life-threatening outcome (adjusted OR 2.00, 95% CI 0.29-13.74) when compared to senior consultants.

Table 4-17 Impact of prescriber grade on error occurrence and severity

Grade of prescriber	Multivariate regression OR (95%CI)			
	Error	Severity		
		Low capacity for harm	Moderate	Severe/life-threatening
Junior registrar	1.43 (0.9-2.26)	Reference	2.25 (0.57-8.94)	2.00 (0.29-13.74)
Senior registrar	0.88 (0.60-1.29)	Reference	1.79 (0.62-5.11)	1.43 (0.30-6.88)
Junior consultant	1.23 (0.84-1.78)	Reference	1.33 (0.30-5.92)	1.42 (0.53-3.82)
Senior Consultant	Reference	Reference	Reference	Reference

Errors occurred during all working days(Sunday-Thursday), however, the highest frequency of errors (162 prescriptions with 22 errors,13.6%) was recorded on Thursdays (see Figure 4-4) whereas workload was busiest on Sundays (589 prescriptions with 55 errors, 9.3%).

Most prescriptions contained more than one drug (80%), but interestingly, the highest frequency of errors occurred among prescriptions which contained one (9.9%) or two drugs (11.9%) (see Figure 4-5).

Multivariate regression explored the potential impact of weekday and number of drugs in a chemotherapy protocol on the frequency of prescribing errors. After controlling for days of the week and the number of drugs in a chemotherapy protocol there were differences for the two explanatory variables, however, these were not statistically significant (see Table 4.18). Errors were equally likely to occur on a Wednesday (adjusted OR 0.82; 95% CI 0.483-1.39), in comparison to Thursday but more than half as likely on occur on Monday (adjusted OR 0.36; 95% CI 0.36-1.08). Furthermore, errors were equally likely to occur with a two-combination drug (adjusted OR 1.07; 95% CI 0.74-1.55) in comparison with one drug protocols and nearly 25% less likely to occur with three drug (adjusted OR 0.72; 95% CI 0.47-1.09) and four drug combination chemotherapy protocols (adjusted OR 0.72; 95% CI 0.25-2.09).

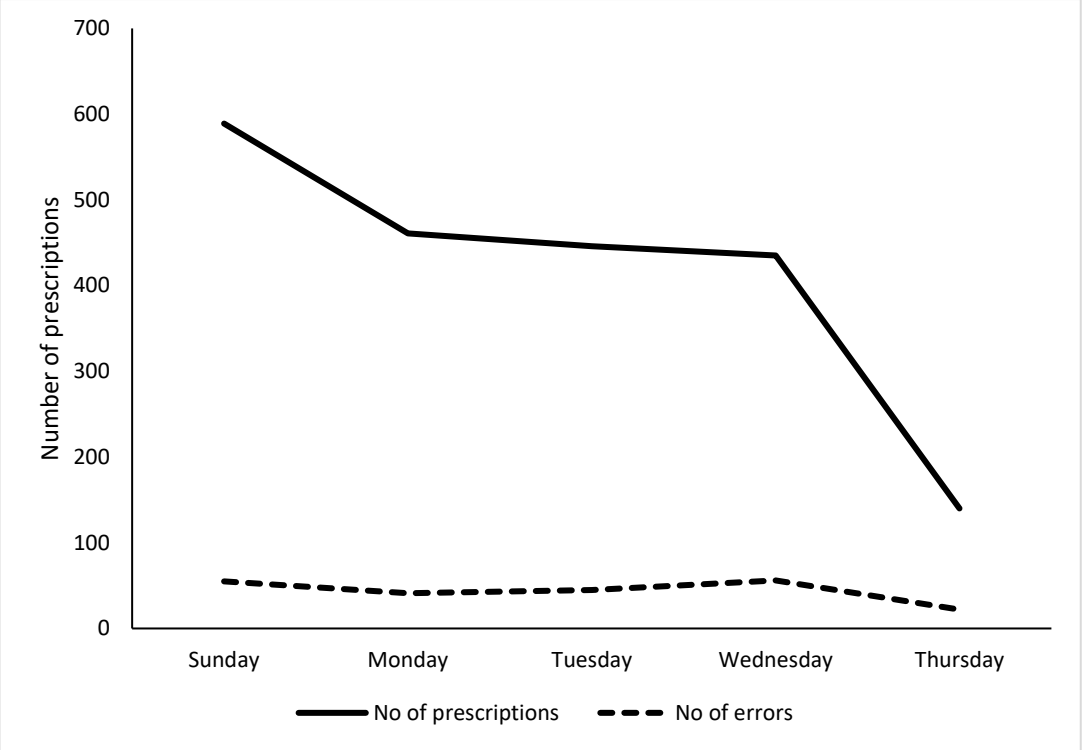


Figure 4-4 Trend in workload and prescribing error among days of week

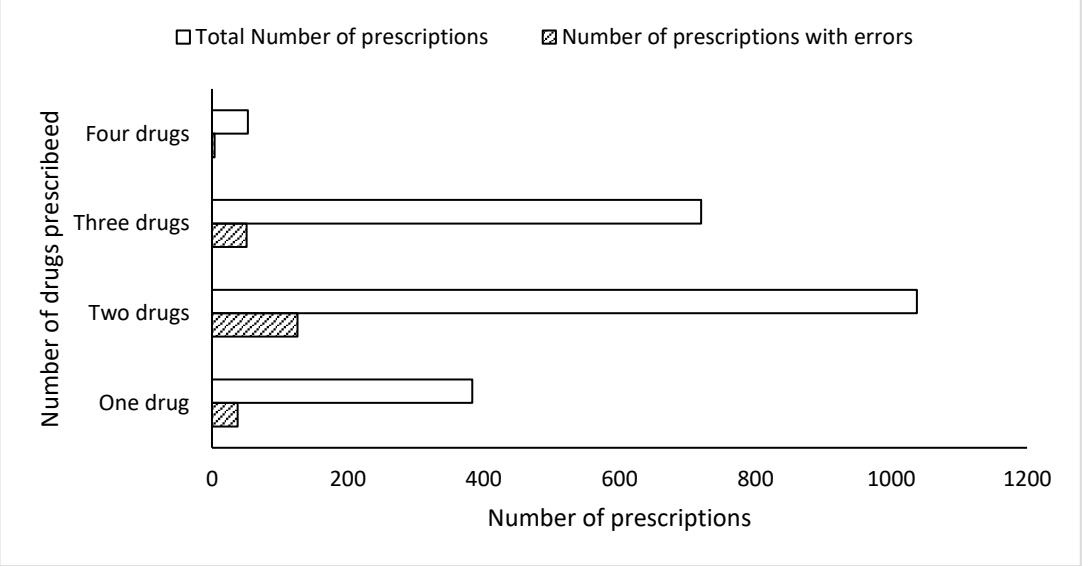


Figure 4-5 Error frequency by number of drugs prescribed

Table 4-18 Results of multivariate analysis for predictors of prescribing errors

Variable	p-value	Multivariable analysis OR (95% CI)
Number of drugs		
One drug	Reference	Reference
Two Drugs	0.71	1.07(0.74-1.55)
Three drugs	0.12	0.72 (0.47-1.09)
Four drugs	0.546	0.72 (0.25-2.09)
Day of the week		
Sunday	0.117	0.66 (0.39-1.11)
Monday	0.091	0.36 (0.36-1.08)
Tuesday	0.11	0.64 (0.37-1.11)
Wednesday	0.46	0.82 (0.483-1.39)
Thursday	Reference	Reference

4.7.7.5 Potential clinical outcomes of errors

The prescribing errors could have impacted significantly on patient care, and potential outcome (see Table 4-19). The majority of clinical outcomes would have been serious/significant harm or life threatening harm (192; 87.7%). Among these, nearly one in ten errors (21; 9.6%) would have the potential to cause life-threatening sequalae if they were not intercepted, mainly due to renal failure, pancytopenia and neutropenic sepsis. Almost half the errors (146, 44.7%) had the potential to cause side effects, some leading to bone marrow and neutropenic sepsis (30, 13.6%). Nearly 33.3% (n=73) of prescriptions with errors would have produced a reduced therapeutic effect in recipients.

Table 4-19 Potential clinical outcome of errors

Potential for harm	Potential clinical outcome	Frequency (%)
Low capacity for harm	No Clinical Impact	27 (12.3)
Serious/significant	Reduced Therapeutic Effect	73 (33.3)
	Bone Marrow Depression and neutropenic sepsis	30 (13.6)
	Increased risk of Side effects	29 (13.2)
	Renal Failure and bone marrow depression	23 (10.5)
	Thrombocytopenia	5 (2.3)
	Worsened Anaemia	5 (2.3)
	Exacerbation of Heart Failure	4 (1.8)
	Increased risk of Heart Failure	2 (0.9)
	Subtotal	171
Life-threatening	Renal Failure, pancytopenia and neutropenic sepsis	11 (5.0)
	Bladder Haemorrhage	3 (1.4)
	Pancytopenia and Neutropenic sepsis and death	2 (0.9)
	Fever and rapid shock	1 (0.5)
	Pancytopenia and irreversible cardiac failure and death	1 (0.5)
	Pancytopenia and peripheral neuropathy and death	1 (0.5)
	Pancytopenia, sepsis and renal failure and death	1 (0.5)
	Sepsis and liver failure	1 (0.5)
	Subtotal	21
Total		219

4.7.7.6 Summary of results

A total of 219 prescriptions (10%) among a sample of 2194 contained 314 errors, of which 87.7% had the potential to cause significant/severe or life- threatening outcome in their recipients. Errors were more commonly due to dose errors or the drug being contraindicated. Prescriptions with cisplatin and carboplatin were more likely to be involved in errors. Junior registrars were twice more likely than senior consultants to write a prescription with a potentially life-threatening error, and errors were more common on Thursdays and Wednesdays which are the two days before the end of the working week in Sudan. Interestingly, errors were also more likely with single and double drug protocols in comparison to multiple drugs.

4.8 Stage Three-Critical incident interviews

Some of the aims of this research were to identify the contributory factors associated with medication errors. Both NPSA and the WHO recommended the use of Root Cause Analysis (RCA), for this purpose (WHO, 2008a;NPSA, 2004a). Other methods that have been used include Failure Mode and Effects Analysis (Kozakiewicz, 2005;Robinson et al., 2006), which is more suited to predicting AEs occurring in hypothetical situations during the preliminary stages of service development. Both methods are established in healthcare but are less adept at understanding human factors leading to error (Senders, 2004). Cooper and colleagues adopted the CIT to understand the human factors involved in anesthesia associated adverse events (Cooper et al., 1984;Cooper et al., 1978). Thus, they identified that equipment failure constituted 14% of the causes contributing to AEs in their study (Cooper et al., 1978).

Pharmacy medication errors studies that employed CIT involved the identification of medication errors through voluntary staff reporting (James et al., 2008), however, this would not have been feasible in this study due to absence of reporting systems at the cancer hospital (identified in Chapter 3). Pharmacist screening of prescriptions and CIT was used in an exploration of prescribing errors among a large cohort of newly qualified doctors (Dornan et al., 2009).

Flanagan developed the CIT in 1954 which he described as a flexible set of procedure for:

"collecting direct observations of human behavior in such a way as to facilitate their potential usefulness in solving practical problems" (Flanagan, 1954; p335).

Flanagan (1974) provided detailed instructions on data collection for CIT and proposed that this could be done using either observations or interviews. The interviews should be worded in a specific way to prevent inferences from research participants and to encourage actual accounts of the critical incident. Research participants would be asked to focus on that specific incident with questions probing the behaviours involved.

Flanagan describes the critical incident as:

"any observable human activity that is sufficiently complete in itself to permit inferences and predictions to be made about the person performing the act "(Flanagan, 1954; p335)

The CIT has many advantages which include focusing on critical events and allowing the researcher to probe into extraordinary events. It reduces rater bias because the respondent is allowed to use their own words to express the reasons why the incident happens. Furthermore, CIT can be used to provide insight into the causes of incidents. However, this method has poor reliability and has the potential to fail in identifying causes of common everyday happenings. The technique has been used in nursing, medicine, dentistry and pharmacy (Fitzgerald et al., 2008;Norman et al., 1992;Cooper et al., 1978;Cooper et al., 1984;James et al., 2008) with a guide published in 2005 (Woloshynowych et al., 2005) to assist its incorporation into medication error research.

Flanagan describes five steps for conducting CIT (Flanagan, 1954); Clarifying the aim of the activity, plans and specifications for carrying out the activity, collecting the data, analyzing the data and interpreting and reporting which were applied to the current study as explained in Table 4-20.

In the current study, pharmacist routine prescription screening during stage 2 was used as a tool to capture prescribing errors. The errors identified during the previous stage were used in critical incident interviews with doctors to identify the associated factors.

Table 4-20 Flanagan's five steps as applied to the current study

Activity	Description
Clarify the aim of the activity	The activity being studied in this research is the preparation and administration of a chemotherapeutic agent
Plans and specifications	This involves identifying a plan of data collection and capturing of critical incidents. In the current study, this involved identifying prescription errors through pharmacist screening.
Collecting data	Flanagan proposed that data collection would be carried out by observation or individual interviews. In the current study interviews were the chosen method of data collection. Interview questions were designed to probe the critical incidents identified. Design of the interview schedule is explained below
Analyzing the data	Reason's Framework of Human error* was used in data analysis. The critical incidents were classified into categories of human error: Slips, Lapses, violations and mistakes. Critical behaviors were categorised using Reason's Framework
Interpreting and reporting	Data was further interpreted and presented as a narrative in the thesis

(Reason, 1997)

4.8.1 Recruitment of research participants

Members of the medical team and clinical directors were aware that the study was taking place and all authorized prescribers were eligible to participate in the study. A total of 44 doctors were involved in writing 219 prescriptions with errors as identified in stage 2 of the current study. However, two doctors were un-authorized prescribers and were excluded from the study. Once a critical incident was identified, research participants were invited in person or by telephone to attend an interview within 96 hours of identification of the incident. Research participants who were not available for interview within 96 hours of the error taking place, were not contacted again regarding the same error. Before the

interviews, research participants were given a PIL (4-6) and two copies of the consent form to be signed (Appendix 4-7).

4.8.1.1 Selection of cases for Critical Incident Technique

During data collection in stage two, it was identified that a number of doctors were involved in more than one error per day. After discussion with research supervisors, it was decided to invite doctors an interview to discuss one error according to the interviewee's preference. However, it was important that the error would have taken place, within 96 of conducting the interview.

4.8.2 Data collection

Doctors who had agreed to participate in CIT interviews were invited to choose a quiet location of their preference. Signed consent was taken before the start of the interview and participating doctors were informed that they had the right to withdraw from the interview at any point. Most interviews took place in the pharmacy medicines information office but a few were conducted at doctors' offices. Research participants were invited to provide answers to the interview and were given the prescription (s) with error as a prompt. In the event of more than one error being identified, doctors were asked to choose one error of their preference to be included in the discussion. Interview questions were conducted in English but the doctors were given the freedom to choose either Arabic or English to answer. Verbal consent was obtained to record interviews using an audio digital recorder.

4.8.2.1 Interview schedule

The interview schedule was adapted from CIT (Appendix 4-8), designed to last between 30-45 minutes and consisted of the following; introductory section, how the error occurred, the prescribing procedure at the time of the incident, description of the environment, perceived reason for the error, how to avoid such an error in the future, needs to prevent such errors in the future and a closure for the interview (Table 4-21).

Table 4-21 Summary of critical incident interviews format

Stage of interview schedule	Description
Introduction	• Greetings. • A brief introduction into the study • It was also confirmed at this stage that the study focused on how the incident took place with no emphasis on the persons involved • Anonymity, confidentiality and freedom to withdraw at any point of the study • A brief description of the critical incident was delivered to the interviewee
Explain how the error occurred	A detailed description of the nature of the incident- Research participant was asked to provide a detailed description of what the incident was and how it occurred
Prescription process	• Description of the process followed during the time the incident took place
Description of the work environment	• Description of the working environment at the time of the incident (Prompts used here were: interruptions, busy, number of patients, inappropriate preparation.)
Reason for the error	• The perception of the interview participant as to the potential cause of the critical incident
How to avoid such errors in the future	• Effective actions to reduce the error prone situations • Ineffective actions
Needs	• Technical and training needs required by interview participants to avoid errors.
Closure	• Gratitude to the participant for taking the time to be interviewed • Requesting a repeat visit should a matter need clarification in subsequent stages of the research

4.8.3 Data Management and analysis

Interviews were taped using (SONY IC Recorder ICD-BX800). Recorded interviews were transcribed *verbatim* and translated into English using the methods outlines in Chapter 2 of the current thesis. Translated data were entered into ENVIVO for storage and data analysis. Framework analysis (described in Chapter 3 section 3.6.7) was used to map emerging themes to Reason's Framework of Human Error (described in section 1.7 of chapter 1) (Reason, 1990). The critical incidents were classified into categories of human error: slips, lapses, violations and mistakes. Critical behaviours were categorised using Reason's Framework as organizational processes and pre-conditions for errors (Reason, 1997).

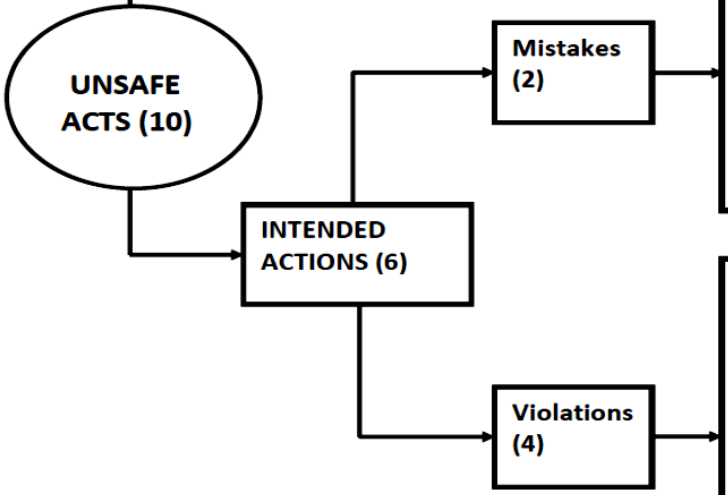
4.8.4 Results

During the first week of data collection an attempt was made to contact each of the doctors involved in the prescribing error identified in Stage 2 of the current chapter. However, the vast majority of doctors were either unreachable or not available within 96 hours of the incident. Hence it was decided to interview doctors involved in errors once rather than repeatedly contacting each doctor for each prescribing error. A total of 10 doctors consented to taking part in the study. Interviews were conducted with four consultants, four senior registrars and two junior registrars to discuss ten critical incidents identified in Stage 2 of the current chapter.

During the interview, the participants were not able to recall the incident and could only do so when prompted. Once prompted, interviewees were able to describe the incident in some detail.

4.8.4.1 Categories of unsafe acts

Following analysis of these interviews, Reason's accident causation model (Reason, 1990)was used to categorise the errors (Figure 4-6). The active failures in this study were identified as slips, mistakes and violations and none were found to be due to lapses. All the four active failures due to slips were caused by attention failures, leading to mis-ordering of a prescription in three incidents and an omission of drug doses for one. Most of the active failures were due to intended actions either caused by mistakes or violations (see Figure 4-6). One of the mistakes was an RBM caused by misapplication of a good rule and the other was caused by a KBM.



Attentional Failures

Critical incident	Description of errors	Level of prescriber	Potential Clinical Consequence
1	The doctor meant to write vinblastine 10mg but wrote 100mg	Consultant	Life threatening agranulocytosis
6	Doctor co-signed prescription which was written by medical officer without checking if the doses were correct	Senior registrar	Minor
7	The doctor wrote the dose of bleomycin as 400 iu instead of 40 iu which was what she originally intended.	Senior registrar	Hypotension, fever, rapid pulse & shock
8	The doctor co- signed a TEC prescription and didn't check that Docetaxel was omitted from the order	Consultant	Loss of therapeutic benefit

Critical incident	Description of error	Level of prescriber	Potential Clinical Consequence
Knowledge- Based Mistake			
2	The doctor didn't realise that he was supposed to write the doses in the prescription	Consultant	Patient would not have his medication
Rule- Based Mistake			
5	The doctor wrote a repeat prescription after being misinformed that the original prescription was lost.	Senior registrar	Prolonged neutropenia

Critical incident	Description of errors	Level of prescriber	Potential Clinical Consequence
Routine Violation			
3	Prescribed carboplatin when the patient's platelets were 85, (min=100). Failed to review the laboratory results appropriately.	Consultant	Severe thrombocytopenia
4	Prescribed Full dose cisplatin (140mg) without ordering laboratory values. Patient requires 75% dose reduction	Senior registrar	Prolonged neutropenia
Exceptional Violation			
9	Prescribed wrong vinblastine on orders from the consultant.	Junior registrar	Therapeutic failure
10	The doctor transcribed the wrong dose of cyclophosphamide; 450mg instead of 950mg.	Junior registrar	Therapeutic failure

Figure 4-6 Analysis of Critical Incidents into slips mistakes and violations

Except for two incidents, most critical incidents had the potential to cause significant life-threatening harm had the prescriptions not been intercepted (Figure 4-8). Interviews were conducted with two of the three doctors who wrote a prescription containing a 10-fold dose which had the potential to result in life-threatening harm. Among the critical incidents discussed, four prescriptions had the potential to cause life- threatening bone marrow suppression.

4.8.4.2 Contributory causes of errors

A number of conditions and factors were associated with the unsafe acts discussed with doctors during the critical incident interviews. Conditions associated with unsafe acts were analysed using Vincent's adaptation (Vincent et al., 1998) of Reason's original error framework (Reason, 1990). These were classified into error-provoking conditions and latent factors (Table 4-22). Doctors were able to give examples of errors that they have witnessed and described the factors that they perceived were responsible for causing such errors.

4.8.4.3 Latent errors

Several organizational and managerial factors were identified as the latent errors that contributed to prescribing error causation. These latent errors were shared amongst the critical incidents discussed in the current study. Among the organizational factors, clinic organization contributed to six critical incidents and culture contributed to five critical incidents (see Table 4-21). Other organizational factors that contributed to prescribing errors were workload, lack of resources, poorly organized hospital records and lack of training. Among the managerial factors, lack of task related procedures contributed to four critical incidents, whereas managerial responsibility contributed to one critical incident.

Table 4-22- Error-provoking conditions and latent factors associated with active failures discussed in critical incident interviews (n=10)

Causes of errors			Unintended actions				Intended actions					
			Slips				Mistakes		Routine violations		Exceptional violations	
			1	6	7	8	2	5	3	4	9	10
Latent Factors	Organizational factors	Resources	+				+	+		+		
		Workload	+	+		+						
		Clinic Organization	+		+			+	+	+	+	
		Hospital Records			+			+				
		Culture	+		+	+				+	+	
		Training					+			+	+	+
	Managerial Factors	Procedures							+	+	+	+
		Responsibility							+			
Error provoking conditions	Patient	Demand						+	+	+	+	
		Complex	+				+	+				
	Individual	Knowledge gaps					+					+
		Professional Responsibility							+	+		+
		Stress			+				+			
	Environment	Busy			+	+						
		Interruptions	+									
	Task	Complicated							+			+
		Hand written prescriptions	+		+	+	+	+			+	+
		Missing information			+			+				
	Team	Supervisions					+					+
		Workload distribution							+	+	+	
		Hierarchies				+				+	+	

4.8.4.3.1 Organizational factors

A number of organizational factors were associated with the errors discussed in the critical incident interviews.

Workload

According to doctors' accounts, the clinics were generally busy which meant that doctors had little time to prescribe. Hence attention to detail was lacking, which had the potential to lead to errors:

> *"If you consider the sheer number of patients that we see in (names the consultant) unit, something like this is inevitable. And you know sometimes, the medical officer may write a prescription and all I do is sign the prescription"* **(Senior Registrar- Critical interview 6)**

Hospital Records

Hospital records were often incomplete and contained insufficient information about the patient. Doctors often needed to contact other departments in order to gather essential information required for the safe prescribing of chemotherapy. The below quote illustrates this:

> *"I thought about the bleomycin cumulative dose¸ so I left the prescription where it was and sent a note to the pharmacy to ask for a medication record profile and check the cumulative dose of bleomycin. Isn't that the right thing to do?"* **(Senior Registrar- Critical incident interview 7)**

Clinic Organization

In five incidents, doctors explained that clinics may run in unofficial areas where there is a lack of supportive clinical and administrative staff. Consequently, patient numbers are uncontrolled and working hours may extend beyond those allocated:

> *"I was in the office and it was crowded as usual. It was just myself and the head of unit. We do some of the work, but he (head of unit) insists on seeing all the patients and then gives instructions to writing a prescription or a referral note to radiotherapy and such. The patient number is an overload...ok I mean the referral clinic is always busy but because it is a planned clinic, all the members of the unit are present, which includes the consultants, the registrars and the medicals. But the referral clinic is repeated the next day here in the office but without the supportive*

> *number of staff. There might be two or three doctor's maximum and we may end up staying till after 2 in the afternoon. It can get really busy in this office"* **(Consultant- Critical incident interview 7)**

Resources

Participants explained that they often faced difficulties when making prescribing and treatment decisions, due to inadequate resources. They explained that sometimes prescribing decisions are made without appropriate assessment of the patient, mainly because important investigations are unavailable at the study hospital. In some instances, investigations essential for making sound prescribing decisions are not funded by the study hospital and require patients, who mostly have financial difficulties, to pay out of pocket expenses. Interviewees felt that the unavailability of essential investigations could lead to prescribing errors or expose patients to unjustified risk from chemotherapy. Below are two illustrative quotes:

> *"the patient came in with an x-ray showing what could be lung mets ... We studied everything and it seemed that the patient had a primary lung so I told the patient that I can't decide on treatment without a CT guided biopsy. The patient went to find out where they could get the investigation done and it turned out that there is one person in the whole of Khartoum who can do it. This one person was on Haj pilgrimage. When the guy came from Haj, he did a CT which showed no evidence of lung mets. …….. If I had given the patient treatment based on the first radiological tests, he would have had side effects..."* **(Consultant- Critical incident interview 2)**

> *".... we may find a new case (patient) who has financial difficulties. If we need to get some more investigations to complete the workup, the patient may not be able to afford the cost of a Computed Tomography, Magnetic Resonance Imaging or an x-ray... and you went ahead and made a decision without referring to those tests, and then you later found liver mets or lung mets. Then here the doctor would have made the wrong decision... yep that's would be an error."* **(Consultant- Critical incident interview 2)**

Doctors explained that there was a lack of appropriate equipment and resources essential for prescribing complex chemotherapy prescriptions:

> *"We just need a protocol booklet to check the doses, we need a calculator to calculate the doses and we need proper working weighing scales. The ones we have don't work and we have to send patients upstairs to get weighed"* (**Senior Registrar – Critical incident interview 1)**

Culture

There was a culture of rigid team hierarchies where junior doctors felt that they were unable to question their seniors. In five incidents, doctors explained that they were "told" by a senior member of the team to write the prescription and felt frustrated that they had to obey orders. One doctor explained how she knowingly wrote a wrong prescription under direct orders from the senior consultant:

> *"... she (meaning the consultant) wanted me to write the prescription to give the patient something. I wrote this prescription knowing full well that the patient won't respond to chemotherapy and that the dose is wrong but I couldn't convince her otherwise and I felt defeated. Honestly, I feel defeated, you know what I mean... I never shout at patients but today I was short-tempered and ended up shouting at patients. I re-checked it with her (the consultant) more than once and repeated 0.19 g or mg and she replied saying just write what I had previously written and please go write the prescriptions. I told her the maximum was 12 and normally the dose is 10mg, she said "I know, just write it as I told you.*" **(Junior Registrar- Critical incident interview 9)**

Doctors tended to obey rules without questioning their senior members of staff, and were afraid of offending them if they did otherwise. A doctor explained how this contributed to an error, because, under the senior consultant's orders, she copied the last dose from the records without checking its accuracy:

> *"The head of unit just told me to write to this patient what he had received before. I opened the file and read the last entry and that's what I wrote on the prescription for… I couldn't question his decision. You know how he can get with us; he can be very upset if we question him."* **(Senior Registrar- Critical incident interview 7)**

Training

New members of staff were provided with little training essential to achieve competency for prescribing chemotherapy. A junior doctor explained that they "*pick up*" knowledge in their daily tasks, rather than being pre-equipped with the necessary training:

> "*the pharmacist contacted me about a prescription, last week, and I told her that I wanted to write dexamethasone instead of methotrexate. You see these names don't mean a lot to me, I haven't come across them before I worked here. I am just now starting to pick up the names."* **(Junior Registrar- Critical incident interview 10)**

4.8.4.3.2 Managerial Factors

Two managerial factors provided the latent conditions for the errors discussed in the critical incident interviews.

<u>Procedures</u>

Procedures for writing prescriptions were not available to doctors and hence doctors would prescribe chemotherapy without guidance and hence may sometimes omit to order or review essential pre-treatment laboratory parameters.

A doctor prescribed carboplatin which had a profound effect on lowering the platelets, without reviewing pre-treatment platelet levels. He explained that ignoring the platelets was a routine violation:

> "*You find yourself looking at all these different parameters and as long as the first one or two look ok, you just go ahead and sign... Things like the platelets, nobody looks at that, I will just look at the haemoglobin and the total white cell count but most people just ignore the platelets."* **(Consultant- Critical incident interview 3)**

In the second incident, essential laboratory parameters were not ordered before issuing the prescription and it was left to pharmacy to identify if the patient required dose reductions:

> *"For this patient, I calculated the dose as 140mg cisplatin on day 1 and the 5FU as 1400mg on days 1,2,3. I asked her (the patient) to go to the lab to get her investigations done and then take both the lab results and the prescription to the pharmacy. But I wasn't too happy with this dose because I thought it was too high and I thought the patient may not be able to tolerate this dose but the dose was correct according to the calculation based on the BSA."* **(Senior Registrar- Critical incident interview 4)**

Responsibility

According to doctors' accounts, team members abandoned their assigned tasks and left clinics unattended. A doctor described how he was left on his own to attend the clinic, when other members of the team left before clinic times:

> *"It was the end of a busy clinic; I had seen the last patient and the other consultant had already left and so had the registrars. I found I was doing all the work and I had a couple of new patients."* **(Consultant- Critical incident interview 3)**

4.8.4.4 Error-provoking Conditions

Several error-provoking conditions interplayed in causation of the active failures in the current study. The error provoking conditions were associated with the patient, the individual doctor, the working environment, the prescribing task and the medical team.

4.8.4.4.1 Patient factors

Doctors explained that the patient was possibly involved in the occurrence of prescribing errors. Patients were usually complex and placed excessive demands on doctors to give them chemotherapy treatment.

Complex patients

Some doctors felt that oncology patients were challenging because the disease is complicated and requires careful decision making. Patients with cancer presented with unique disease characteristics and the many options available mean that prescribing decisions need to carefully tailored to each patient. Below is a quote illustrating this:

> *"You sit in one of those primary medical centres and it's the same story with every patient who comes in. They may have tonsillitis, a chest infection, urine infection, malaria, the story is simple but with a cancer patient it's complicated. Each patient is a different story. The choices are very hard and you may want palliative or radical treatment. You may want to decide on concomitant radiotherapy or chemotherapy followed by radiotherapy or one of these treatment modes without the other, you may want to give neoadjuvant. Each patient is a separate entity, and that needs time, needs time*." **(Consultant- Critical incident interview 2)**

Another aspect that complicates the management of oncology patients are the considerable changes in the patients'' clinical status requiring the treating doctor to closely monitor the patient and identify how to modify the treatment accordingly. Doctors perceived those challenges to pose a risk for errors.

One example was described by a doctor when a patient arrived to receive their subsequent chemotherapy cycle. The doctor prescribed chemotherapy without assessing the patient, however, it was discovered later that he patient had a poor performance status and would not be fit to receive chemotherapy. It was evident from the doctor's narrative that this practice, although a violation, was common:

> *"Most of the time, it's the co-patient that comes to see us rather than the patient. The Prof had a go at me before because I had written a prescription for chemotherapy when the patient's performance status was poor and she wasn't going to tolerate the chemotherapy well. I had not seen the patient myself but relied on the assessment of the co-patient, I asked the co-patient if they thought the patient would be able to tolerate the chemotherapy. I had also written in the file, "patient not seen"."* **(Senior Registrar- Critical incident interview 1)**

<u>Patient demands</u>

Patients and their relatives were perceived to put unreasonable demands on the doctor to write a prescription. These demands resulted in a number of outcomes. For example, one doctor felt pressurised to write a prescription without assessing the patient.

> *"I know he (Head of department) says we shouldn't write the drugs without seeing the patient, but when the co-patient (relatives or carers) comes and he is asking you to do him a favour, then I am forced to write the prescription. I can't ask him to go home and bring the patient to the outpatient clinic."* **(Senior Registrar- Critical incident interview 1)**

Another example is when doctors prescribe unnecessary chemotherapy because the patient demands treatment. One of the junior registrars explained that the chief consultant at her clinic would use non-evidence based chemotherapy protocols that to keep patients satisfied:

> *"We had a patient with renal cancer and the chief consultant wrote bleomycin and vinblastine and I really felt sorry for the patient. The disease doesn't respond to chemotherapy but they write the drugs to keep the patient happy. Today, I was*

thinking about this, I thought why don't they tell the patient that the disease won't respond to treatment anymore." **(Junior Registrar- Critical incident interview 9)**

4.8.4.4.2 Individual Factors

Knowledge

Doctors implied that some team members lacked the skills and knowledge or access to prescribing resources, essential to prescribe chemotherapy, safely:

"One of the main reasons in my opinion is not having the knowledge or not having access to information sources. If the doctor doesn't have the right knowledge and this could be for any reason. It could be that he hadn't seen the situation before or that the disease is very rare and the doctor hasn't seen a similar case in a very long time. The doctor may also know the regime to be used but doesn't know the dose, ok. So, absence of knowledge is the key to causation of errors." **(Consultant-Critical incident interview 2)**

One doctor explained how lack of knowledge about prescribing chemotherapy can lead to errors and leads to frustration:

"I only realized that we give dexamethasone and prophylactic antibiotics with docetaxel when a patient asked me to write the supportive care for docetaxel. I looked very puzzled and if it wasn't for x (the porter) I wouldn't have known. She told me what to write and I felt very angry at myself. I was upset at not knowing this basic information." **(Junior Registrar – Critical incident interview 10)**

Professional Responsibility

In three incidents, two of which were a violation, doctors did not assume professional responsibility when prescribing chemotherapy. One example was a doctor who had temporary eyesight limitations but continued prescribing the wrong doses:

"It's possible that I wrote this prescription when I had keratoconjunctivitis and wasn't wearing my contact lenses... I can't wear glasses because they affect the shape of the eyes and can cause bags under the eyes. I had keratoconjunctivitis for a month and the doctor had asked me to stop wearing contact lenses. You must have noticed that the other interns would laugh at me because I would put my seat quite close to the front because I couldn't see. I also have astigmatism. I couldn't see the words clearly and the letters were swimming in front of my eyes and they would

> *ask me to wear the glasses, but I would rather die than go around with eyeglasses and ruin the shape of my eyes*." **(Junior Registrar- Critical incident interview 10)**

Another example is a consultant that would pre-sign empty prescription forms and leave them for junior doctors to fill:

> *"... the boss has a policy; he says we shouldn't let a patient leave the clinic without a prescription in their hand... He even pre-signs some empty prescriptions and the empty treatment plans from the patients' files and leaves them to us or the medical officer to fill, saying that he doesn't want someone to come looking for him for a consultant signature."* **(Senior Registrar- Critical incident interview 4)**

Stress

Doctors worked under stressful conditions where they experienced fatigue, expressed in not showing interest in their patient. Under the influence of stress and fatigue, doctors stated that they felt the need to quickly write a prescription and dismiss the patients:

> *"I was left on my own and you know, I am a new consultant. I was tired and had seen so many files in front of me and the patient thrust the lab results under my nose as I was walking out of the clinic. I wasn't concentrating on the patient and all I wanted was to leave as soon as possible... I just wanted to get rid of the patient, so I looked at some of the results and not looked at the others well enough and just put a quick signature on the lab results form, saying that it's ok to go ahead with the chemotherapy."* **(Consultant- Critical incident interview 3)**

4.8.4.4.3 Environment factors

The interview participants talked about busy clinics and how they thought this could contribute to errors. One doctor explained that he wouldn't have enough time to review the patient's medical history appropriately before reaching a therapeutic decision. And in some instances, he would make a decision that is not appropriate:

> *"The outpatient clinic was busy, there were more than 60 people sitting, each one of those has a pile of files to look through. I can't read all the file, I can't read all the information, I can't go through all the X-rays. Therefore, when I give a decision, it may not be tailored to the patient, it may not cover all the aspects in that patient. I may have seen a fraction of the things and built a decision on partial information."* **(Consultant- Critical incident interview 2)**

4.8.4.4.4 Task factors

Complex tasks

Doctors explained that the calculations for chemotherapy prescriptions were often complex and may rely on others including other healthcare teams to assist in the tasks:

> "*The BSA calculation is not straightforward but I always do it. But for example, for patients on carboplatin, I wouldn't write the dose but just the target AUC and such. I would order a serum creatinine and rely on the pharmacy to calculate the dose. I would never repeat a dose of carboplatin but write the serum creatinine and leave the rest to pharmacy.*" **(Consultant- Critical incident interview 1)**

Handwritten Prescriptions

Doctors prescribed chemotherapy on empty prescription forms, which required that they had to rely on their memory to write down all the different elements of the prescription. A mistake occurred when a new consultant who had no previous experience in the hospital wrote a number prescription where he omitted the doses. He was interviewed for one of these prescriptions and explained that he omitted the doses because he felt that prescription writing was unclear to him:

> *"I have just started working here and have just written those few scripts, the ones that you see without the doses... You know I have just come back from abroad so I don't know the system very well and I saw that some prescriptions (not written by me but written by others) would be sent back by the pharmacy with a note saying things like this needs a dose reduction, or the patient may need another alteration to the prescription. The pharmacy calculates the surface area, they calculate the dose reduction, ok? So, for me, it wasn't clear what I had to do and thought that if I just wrote FAC, they would calculate everything as in the protocol...*" **(Consultant - Critical incident interview 2)**

Unreliable information

In two incidents, doctors explained that the information required for prescribing chemotherapy may be absent or unreliable, contributing to decision errors:

> *"We had a patient who was seen by a doctor in one of the large hospitals, she referred her for a fine needle biopsy. The results were carcinoma in situ. The patient had a lump and she had lymph node involvement. You know that carcinoma in situ*

should be a lump, it could be 2cm or even bigger but it needs to be very localised and without mets or axillary involvement. Because it is carcinoma in situ that hasn't yet gone beyond the basement membrane. We decided on neo adjuvant therapy which is the right decision according to the clinical presentation but not according to the pathology results. The decision is correct in view of the axillary involvement and in view of the local involvement but not in view of the results of the fine needle. So, we decided to give the patient a cycle of chemo and then to repeat the investigation as true cut. It would have been better in this situation to ask the patient to repeat the investigation before starting the chemotherapy." **(Consultant- Critical incident interview 2)**

4.8.4.4.5 Team factors

Workload distribution:

Doctors believed that workload distribution within the team was unfair because some doctors were assigned more tasks than others. One registrar explained that, in her unit, the consultant was well known to allocate most of the work to junior staff, because she would only review the patients she sees in her private clinic:

"I am the first one who comes to the referral clinic and take most of the files and put them on my desk. I usually give the other registrar a smaller pile of files because you know he is not capable of reviewing all the files. The consultant doesn't review any file except when the patient is a private patient of hers in the private clinic or it's a patient that she knows otherwise. She won't waste her time with the rest of the patients. So, I know which patients are her private patients and I put their files onto her desk." **(Junior Registrar- Critical incident interview 9)**

Team hierarchies seemed to be rigid and, doctors felt unable to ask questions of their senior colleagues. Hence, even against their better judgement, doctors would violate normal procedure if they had been asked to do so by their consultant, as illustrated below:

"But the boss is always right, and I can't overrule his decisions. If he decides that we should write a prescription without checking the labs then so be it. This is what we will do. I know pharmacy don't like it and they say that we send the patients without checking their labs knowing full well that some of these patients may present with poor renal function because of the nature of cancer of the cervix, they may present

> *with obstructive nephropathy so I suppose I need to know the serum creatinine before prescribing the dose."* **(Senior Registrar- Critical incident interview 4)**

Supervision

Doctors suggested that supervision from senior members of the team was absent in many situations, leading junior doctors to continue prescribing drugs without carrying out investigations necessary to assess patient's response to treatment:

> *"There are people who just follow the previous dose without doing the calculations in case the patient's parameters have changed. For example, the other day, the patient with HD came. He previously had ABVD, six cycles, and then disappeared for so many months. He came with recurrence, he hadn't come since March (9 months ago), so my junior colleague re-wrote the same regime. The patient received two doses, and was on his third dose, I calculated his cumulative dose and realized that he had received his total lifetime dose of doxorubicin. So, I wrote on the file that he had completed his cumulative dose."* **(Senior Registrar- Critical incident interview 1)**

Defences

Doctors relied on pharmacists as a defence against prescribing errors. One consultant explained that when he wrote a prescription, he expected pharmacy to identify any particular issues that he may have missed and required the prescription to be modified:

> *"There may be something that we are not aware of or something that we have missed. I expect you (meaning anyone from pharmacy) to send us a note to inform us of whether a dose reduction is needed or anything else."* **(Consultant- Critical incident interview 2)**

> *"They use regimes and doses out of this world but it's good that pharmacy manage to change most of them."* **(Junior Registrar- Critical incident interview 9)**

Other doctors relied on senior members of their unit to check the acuracy of prescriptions:

> "...*there are others that I may have forgotten or maybe I can't recall certain details, so, I would ask (names senior member of the medical team). I would ask someone for the dose of the protocol."* **(Senior Registrar- Critical incident interview 1)**

4.9 Stage four- Focus Group Interviews

During the collection of data in stage 3, it was evident that interviews were conducted with less than one quarter of doctors involved in prescribing errors. The purpose of the current stage of the study was to conduct focus groups to explore the opinion of a larger number of doctors who were involved in errors. The aim of this focus group study was to acquire more insight into the experiences and opinions of doctors, regarding the type, contributory causes and management of prescribing errors.

4.9.1 Development of the focus group schedule

The focus group schedule (Appendix 4-9) was divided into six sections. The first section was an introduction and consisted of welcoming the focus group participants, assuring confidentiality anonymity and freedom to withdraw and explaining the aim of the study. This section also included technical aspects of the focus group discussion which was a discussion of the language to be used and asking the participants to consent to the discussion being audio-recorded. The areas to be covered during the focus group were discussed in this section as well as a brief introduction and definitions used in medication safety research.

The second section of the focus group discussion intended to probe the safeguards participants follow to protect patients against potential harm. The discussion was steered to make sure the participants covered; training and CPD, competency and prescribing, knowledge about drug, evidence based medicines and how they verify doses and check for contraindications, the use of second checks, meetings and grand rounds, patient consent and the procedure followed when monitoring patients and following them up, the use of abbreviations and lastly recording in patient records.

The third part, was designed to explore the experiences of the participants with regards to errors; if they were involved in an error, if they believe or had witnessed an error that resulted in patient harm and what they perceived were the most common types of errors.

The fourth part of the discussion aimed to understand the pariticpants perceptions about the causes of errors. Each member of the group was given a piece of paper and asked to recall an error that they had either witnessed or were involved in and were asked to write down what they had thought the factors contributing to those errors were (Appendix 4-10). Disscussions were encouraged to cover the typical areas associated with error prone

conditions such as workload, interruptions, patient knowledge, prescriber training and knowledge, availability of resouces necessary for prescribing, patient pressure, work stressors, team work and busy work environment, job satisfaction and work related fatigue.

The fifth part was designed to identify the types of measures, the doctors use or think can be used to manage errors. The doctors were asked to imagine if themselves or a colleague were involved in a prescribing error. They were asked to discuss together how they think they will manage the error, report, learn from it and how they will manage the patient should they be affected.

The fifth part relied on findings from the first focusing exercise, where the contributory factors were written on a flipchart. Focus group participants were asked to suggest solutions to the contributory factors and debate the proposed solutions. The discussion points, were steered to cover findings in stage three (in this chapter) and previous medication error research and these were; environment factors: organization of the outpatient clinic, task based factors: patient files, design of a pre-printed chemotherapy prescription, patient education, pre-clerking clinics, team issues : number of staff, staff mix and work load allocation

The sixth part was a second focusing exercise where a bar chart displaying the frequency and nature of prescribing errors identified in stage 2 (of the current chapter) was distributed among the focus group participants (Appendix 4-10). The participants were given 10 minutes to debate and discuss the high risk areas of prescribing. The focus group facilitator steered the discussion to ensure that the following areas were discussed: potential impact of prescribing error on patient outcomes, frequency of prescribing errors and high risk areas. They were then invited to discuss the priority area and priority interventions to be addressed. Topics were steered to ensure that focus group participants covered the prescribing task, work load allocation, support for prescribers from other staff, how safety culture has been used in other areas of high risk to improve safety, how to report and learn from errors, blame and accountability.

The focus group was concluded by thanking participants for taking time to contribute to the research and inviting comments and questions.

4.9.2 Recruitment of research participants

Purposive sampling was used to recruit doctors in this study. At the time of the study, 42 medical doctors were authorised to prescribe chemotherapy and all had been involved in prescribing errors as identified in stage 2 of the current chapter. During the course, of the study, a number of doctors participated in various exercises; 4 were involved in the key informant interviews, 10 in the critical incident interviews and 1 in error validation. The remaining, 27 doctors had not participated in this research, so far. Doctors were invited to participate in three focus groups with each group consisting of 4 members and composed of one grade of prescriber; consultant, senior registrar and junior registrar

Prospective focus group participants were invited in person and each was given a PIL (Appendix 4-11) and consent form (Appendix 4-12) to read before agreeing to take part in the study.

4.9.3 Data collection

Participants were asked to choose a location that was suitably furnished to allow participants to see each other's' faces and where interruptions would not occur. All participants agreed that a lunchtime meeting would be most appropriate where refreshments were provided. Focus group discussions were conducted in the medicine information department at the hospital and one was conducted in the doctor's mess. The focus group exercise was conducted using the general principles outlined in Chapter 3 and guided by the focus group schedule outlined in section 4.9.1 (Appendix 4-9).

4.9.4 Data entry and management

Focus group discussions were recorded using a digital recorder (SONY-ICD BX800) and transcribed verbatim in Arabic. The verbatim discussions were translated using the principles outlined in chapter 2. Translated data were entered into ENVIVO for storage and data analysis. The emerging themes regarding contributory factors were analysed using Framework analysis based on Reason's Framework of Human Error (described in section 1.7 of Chapter 1).

4.9.5 Results:

During focus group discussions, doctors were able to describe their own methods in ensuring prescriptions were safe and that errors were reduced. They were able to recall incidents when prescribing errors, dispensing errors and administration errors occurred and describe situations when patients have experienced harm in consequence. Participants from the three focus groups were unaware of patient safety culture and had not heard of the term before the exercise was undertaken. Nevertheless, focus group participants were able to explain the contributory causes of prescribing errors at the study hospital and propose possible solutions.

4.9.5.1 Examples of patient harm:

Focus group participants stated that they would only be aware of a patient being harmed by a prescribing error if the patient presents at the cancer hospital. However, in most situations patients would seek medical care elsewhere.

> *"An error that harmed the patient? This depends on whether the patient comes back to us with problems. Most of the time the patient doesn't come back with issues and they may go somewhere else"* **(Consultant 1- Focus Group One)**

However, each group was able to recall incidents where patients were harmed as result of a prescribing error. Two doctors described the consequences of transcription errors:

> *"Another problem occurs when the registrar, transcribes the second dose. This happens more commonly when prescribing Ifosfamide. We usually give double the dose of mesna to ifosfamide, so when the registrar writes the dose, they may confuse the doses and write the double dose for the ifosfamide instead of mesna. For example, I have a patient who had 8g of ifosfamide, that's double the dose and when I enquired about what happened, the registrar said he didn't know the dose and transcribed it incorrectly. ……. the patient had severe abdominal pain and had prolonged neutropenia. Her total white cell count has still not improved even after we reduced the dose on the third cycle. When she presented for the fourth cycle her white cell count was extremely low and, it's been over a month now, but we can't give her the fourth dose."* **(Consultant 2- Focus Group One)**

> *"I remember a vincristine dose that was written incorrectly, I don't know if you were working with us at the time, but you know the maximum dose is 2mg and the patient*

was prescribed 8mg instead. The patient survived but he was admitted to the ward and stayed for several weeks. He was in pain and constipated and had poor sensation on both feet and hands. The drug was prescribed wrongly and was dispensed by pharmacy as such and given by the nurse. I mean something like this could have been checked by the nurse or the pharmacist." **(Senior Registrar 1 – Focus Group Two)**

4.9.5.2 Latent factors associated with errors:

Focus group participants described the contributory factors associated with prescribing errors and situations where patients were harmed. These factors were related to the culture, the working environment, the task of prescribing, the individual doctor and the patient.

4.9.5.2.1 Culture

Focus group participants from the junior prescriber grade were particularly aware of the culture at the cancer hospital and described errors that occurred because they felt unable to question their superiors.

"*We are junior doctors so we just do what we are told most of the time. I will give you an example. I had a patient with colorectal cancer and the consultant wrote on the plan for gemcitabine and taxol. I just stared at the file in utter disbelief…we all know that this regimen has no role in that specific malignancy and ok so the patient had no response to other first line drugs but that doesn't mean that they should be given chemotherapy for the sake of it. So, I wrote the prescription and yes pharmacy contacted me to clarify the regimen but I couldn't say anything. I think that I asked them to refer the query to the consultant"* **(Junior Registrar 2- Focus Group Three)**

In one situation, a patient experienced a fatal AE because her consultant prescribed a dose of 5-Fluoruracil administered over 4 days, rather than the recommended 21 days. The junior doctor questioned the prescription but she felt unable to act because the consultant had insisted to proceed with the treatment:

"What can you do when you know for sure that this will kill the patient. He wrote the dose and I questioned it but he said its ok and he has tried it before and you know the rest...yes the patient died two weeks later with neutropenic sepsis, dehydration and severe mucositis" **(Junior Registrar 1- Focus Group Three)**

4.9.5.2.2 Environmental factors

Doctors prescribed chemotherapy in outpatient clinics that were not appropriately organized. The clinics were crowded and patients attended in no particular order. Furthermore, clinics were inadequately furnished and lacked equipment pertinent to conducting appropriate patient examination.

> *"But some patients just attend clinic for no reason, you see them at each clinic, the first clinic and the one at the end of the week. The patient may see one doctor and instead of leaving, they go to see another doctor in the unit, they have no control on the movement of patients in the outpatient department."* **(Consultant 2- Focus Group One)**

> *"The building itself barely qualifies as a health care institution, there are no designated areas for washing hands, no ceiling fans or air conditioners, the ventilation is very poor. If the building is in a good state and is made to be more suitable, we can see more than the number of patients we do at the moment."* **(Consultant 1- Focus Group One)**

Poor organization of the clinics meant that doctors faced a number of interruptions and consequently lost their concentration. The patient usually presented to the clinic without the necessary investigations and hence the doctor often had to interrupt the consultation to obtain those. Below is an illustration of this:

> *"The clinics are usually crowded and patients come and go. So, the patient may come in and I would ask them to go back and get their investigations, when they get the investigations, I may discover that the weight isn't done, so I have to send them again to get weighed. By the time, I want to write the prescription I may forget my intentions and say I was supposed to prescribe allopurinol but I would have forgotten by that time. After the patient, has left and at the end of the day, I might remember what I was supposed to prescribe. These things happen a lot…the environment doesn't help."* **(Junior Registrar 3- Focus Group Three)**

4.9.5.2.3 The Task of prescribing

Discussions during focus group exercises revealed that doctors were faced with a number of difficulties during the prescribing process. Access to essential information was usually hampered by incomplete patient files or one that were disorganized.

> *"The files are always in a mess. If you need to look for something, you have to search the whole file, you have to look for the last page of entry. You may want to read the last follow up and finding the specific page takes a long time. This is a problem in the outpatient department specifically as it is very busy. We always have to ask the patient about the last follow up because you are never sure where it was recorded"* **(Senior Registrar 2- Focus Group Two)**

Furthermore, doctors sometimes felt unable to carry out a thorough assessment of their patient. This presented difficulties with calculating doses when the necessary investigations were not available or were only available at extra cost to the patient

> *"I just want to say that some investigations are very costly and they may not available at the hospital or are not free of charge. I mean mainly liver function tests they are too expensive for the patient and most of the time, they can't get those done."* **(Senior Registrar 1- Focus Group Two)**

4.9.5.2.4 The Individual Doctor

During focus group discussions, doctors stated that errors may occur if the individual doctor has poor knowledge or may have the knowledge but does not follow best practice.

> *"…Some of the registrars start on the chemotherapy prescribing without having the knowledge. A lot of those doctors haven't seen chemotherapy before and have no idea about prescribing….."* **(Senior Registrar 2- Focus Group Two)**

> *"Another test which is always ignored are the baseline ECHO investigations which are required to be done before giving anthracycline therapy for patients over the age of 50. I have seen one patient who was receiving her first cycle of ABVD. The nurses called me to the chemotherapy day ward because the patient developed chest pain. I ordered ECG and echocardiogram which showed reduced ejection fraction and obvious signs of cardiomyopathy. You know what? The echo report stated that the cardiomyopathy was due to chemotherapy. But that wasn't true because she had just had a tiny fraction of 25 mg and it's not possible to develop*

> *such advanced cardiomyopathy so soon and after such a small dose. The patient has been admitted for observation and today when the consultant was made aware of this issue, asked that no anthracycline therapy should be started in any future patient without carrying out baseline echo. Sometimes when a problem happens, we realise that these things are important and are meant to be done for specific reasons."* **(Senior Registrar 3- Focus Group Two)**

Some doctors believed that errors occurred because some members of the nursing team did not possess the necessary skills and knowledge to administer the chemotherapy, properly. One doctor described how a patient was harmed by an administration error, despite the prescriber giving appropriate instructions:

> "*they gave the patient the vinorelbine dose via the intramuscular route. She called the pharmacy to say that she had given the patient folinic acid and the patient started screaming, when the pharmacist arrived on the ward, she discovered it was vinorelbine. The patient was prescribed vinorelbine but the nurse was not able to read the prescription or the administration instructions. We couldn't find an antidote anywhere but the patient was admitted and was given supportive care."* **(Junior Registrar 3- Focus Group Three)**

4.9.5.3 The patient

It was revealed during focus group discussions that the patient could also contribute to an error. Patients presenting for chemotherapy were usually very ill and had little information about their disease and chemotherapy. This may lead to harm.

> *"Some patients experience harm because they don't follow the doctor's instructions. Especially those that use traditional medicines. Problems happen when the patient combines these with chemotherapy. I mean the patient may get better using the chemotherapy but if they are using herbal medicines or any traditional medicines, they would attribute the benefits to that… We had a patient, I think he was with Dr D unit's, he had lymphoma, no CML, he was taking……. Glivec and then started to take that new herb, what is it called…Oh yes moringa. So, he started taking the moringa and he felt that he had improved and stopped taking the glivec……he came back for his six months' review but it was too late……. there was nothing to do because he was in blast and it was too late to help him"* **(Senior Registrar 2- Focus Group Two)**

Patients were often complex and required close monitoring and if the doctor failed to monitor the patient appropriately, errors may occur. Below is an illustration of this:

> *"Our patients are usually very ill and may lose considerable weight during treatment and if the doctor doesn't check the weight regularly then there will be a problem."* **(Consultant- Focus Group One)**

4.9.5.4 Defences and error management

During discussions, doctors listed a number of system defences that they personally used to prevent errors from occurring. These defences were focused on error management and error prevention.

In situations where the doctors were busy, they usually relied on other members of the healthcare team to rectify errors.

> *"I think that may be due to the fact that a lot of times we would prescribe the chemotherapy without looking at the pre-chemo investigations. We rely mainly on pharmacy to check those doses when the investigations come through……. So, we will send the patient to be weighed but that usually takes a long time so we ask them to go to pharmacy with their new weight. They will usually calculate the creatinine clearance and they know the dose reductions. We know they will give us the correct and appropriate dose for the patient."* **(Senior Registrar 2-Focus Group Two)**

According to participant's accounts, errors were managed by informing the person involved to bring their attention to the matter and prevent repetition.

> "*If this happens to me, I would always call the doctor involved and explain to them that it needs to be done this way rather than the way it was done in. I wouldn't punish them but I would let them know about the error so that it is not repeated.*" **(Consultant 2-Focus Group One)**

Doctors proposed solutions to the issues discussed. They thought that clinic re-organization was an important issue to be prioritised, in order that patients are seen in less disorganized environments.

> *"Usually, there are four of us in one room and each doctor has one patient and a number of relatives with them. I mean if each room has a maximum of one*

> *consultant and one registrar and patients can come in one by one, then we would be able to concentrate better."* **(Junior Registrar 3- Focus Group Three)**

Members of focus groups revealed that they thought pharmacists were important in verification of prescriptions and prevention of error. It was proposed that closer liaison with pharmacy would reduce chemotherapy related prescribing errors.

> "*one of the best solutions in my opinion is to keep a close contact with the pharmacy when prescribing, I meant the unit should have direct access to pharmacy... this is important."* **(Consultant 3- Focus Group One)**

A further solution proposed by a participant in one focus group, was a change to the system followed in prescribing and administration of chemotherapy

> "*…on the paediatric ward, we had to do some changes to our prescribing so that more than one nurse is involved and if an error occurs, more than one person can spot the error. We divided the long doses each into four doses. So instead of putting the whole dose into one iv bag and infusing it over 24 hours, these are now split into four bags, each over 6 hours. That way we make sure that the patient has the drug over the required time and again if there was a dose error, it may be spotted. Another thing that we noticed was that nurses don't know how to calculate the dose, so instead of prescribing just the dose we would write instructions for the nurse on how to reconstitute the dose, so we would write for example to be reconstituted with this many cc's of normal saline and remove this many cc's of drug and add to the bag and so forth"* **(Senior Registrar 2-Focus Group Two)**

4.10 Discussion

The current study identified that one out of ten prescriptions (219 in 2194) contained at least one error, of which most (88%) had the potential to cause serious/ significant harm or life-threatening harm. Errors were caused by a number of error and violation provoking conditions and influenced by several interlinked latent factors. These factors were embedded in the culture and organization of the study hospital. Errors were frequent and repeated and prescribing of chemotherapy took place in under resourced environments where error defences were absent. Although to our knowledge, all the prescriptions with errors identified in stage 2 of the current chapter were rectified before reaching the patient,

evidence from focus groups (stage 4 of the current chapter) revealed that patients had been harmed as a result of prescribing errors and one fatality was described.

This is, to our knowledge, the first mixed methods study that identified prescribing errors and their contributory causes in a cancer hospital in the EMRO region. Medication safety research is not commonly undertaken in developing countries (Wilson et al., 2012) with very little research concerning medication errors associated with chemotherapy prescriptions (Oberoi et al., 2014). However, prescribing errors in cancer chemotherapy are common in both developing countries (Oberoi et al., 2014, Mathaiyan et al., 2015) and developed countries (Gandhi et al., 2005a, Elsaid et al., 2013).

Similar to the methods employed in this study, the most frequently used research method for detection of prescribing errors was through routine pharmacist prescription screening (Lewis et al., 2009, Tully et al., 2009). A review of 65 studies focused on prescribing errors in general medicine, paediatric and mental health settings identified that pharmacist routine screening of prescriptions was the most common (40%) among prescribing errors studies (Lewis et al., 2009). Likewise, most prescribing error research in chemotherapy involved pharmacist screening of prescriptions (Alcácera et al., 2001, Díaz-Carrasco et al., 2007, Gandhi et al., 2005a, Garzás-Martín de Almagro et al., 2008, León Villar et al., 2008, Markert, 2009, Nerich et al., 2010, Ranchon et al., 2011, Slama et al., 2005). It is worthwhile that routine screening of prescriptions by pharmacists serves as a useful resource for the identification of process-based errors (Lewis et al., 2009). A small number of studies have used other methods (Ford et al., 2006, Huertas Fernandez et al., 2006, Walsh et al., 2009, Oberoi et al., 2014). For example, a study exploring prescribing errors associated with oral chemotherapy collected data from record review and patient/carer interviews (Oberoi et al., 2014).

The causes prescribing errors have been explored using qualitative methods (Tully et al., 2009). A review of 16 prescribing error studies, focusing on identifying causative factors, revealed that almost all employed qualitative methods which included semi-structured interviews, structured interviews and observational methods. The current study employed the CIT used previously in similar research in general medicine (Dornan et al., 2009). Doctors from UK based hospitals were invited for an interview within 96 hours of a prescribing incident, and the interview data were analysed using Reason's Human Error Theory (Reason, 1990). This was similar to design of the current study design but poor response meant that, unlike similar research (Dornan et al., 2009), only ten doctors were interviewed. Nevertheless, analysis revealed a number of error and violation provoking conditions which

were common to most of the conditions when the prescribing error occurred. Although the doctors needed prompting to remember the error, most were able to give detailed accounts of the associated conditions and factors. For example, doctors remembered the incidents once they heard the patient's or saw the actual prescription. Similar prompts were used in previous prescribing error research (Franklin et al., 2011;Dornan et al., 2009).

4.10.1 Cancer distribution

Cancer distribution in this study was different to the data published in Sudan because data, in the current study, was extracted from patients who presented for day case chemotherapy and excluded patients requiring in-patient treatment. Statistics from Sudan show that breast cancer is the most common presentation among cancer patients, followed by leukaemia, lymphoma and prostate cancer (Saeed et al., 2014). Cancer distribution among patients who presented for day case chemotherapy during data collection was also highest for breast cancer but leukaemia patients were not included in the sample, in this study, because the disease is commonly managed in inpatient settings. The proportion of patients with prostate cancer was also fewer than expected, although it is the second most common cancer among Sudanese men (Saeed et al., 2014). This would be expected because drug management of the disease mainly involves oral hormonal therapy. Only a small minority of patients, who develop hormone resistant disease (Chan et al., 2007), would be managed using chemotherapy administered in the chemotherapy day unit.

4.10.2 Frequency and potential clinical significance of prescribing errors

The frequency of prescribing error in the current study (10%) was comparable to those reported in previous studies (Lewis et al., 2009). For example, a review of 65 prescribing error studies identified that the average prescribing error rate was 7% (2-14%). Unfortunately, the authors did not include a list of the medications studied and hence it was not possible to identify if chemotherapy drugs were included in the reviewed studies. However, when compared with errors in chemotherapy prescribing, a number of challenges are encountered. The reported chemotherapy prescribing error rate varied (0.31% - 100%) for a number of reasons: study aims and objectives, study design, different definitions for errors, different settings, and use of oral or intravenous chemotherapy (Gandhi et al., 2005b;Ranchon et al., 2012;Ranchon et al., 2011). For example, Huertas-Fernandez and colleagues (2006) reported an error rate of 100% in manually written prescriptions in

comparison with computerized prescribing, most of which were omission errors (83%). However, in this study setting, doctors were never required to write the pre-medication, hydration, rate of administration or final concentration, because these details are included in the standardized administration template where the pharmacists transcribed the prescription details. Hence in current study omissions of these details were not considered an error but have been in other studies (Huertas Fernandez et al., 2006).

When compared with other research in chemotherapy prescribing, errors which have the potential to cause adverse events were found to be 12-50% (Díaz-Carrasco et al., 2007;Oberoi et al., 2014;Walsh et al., 2009), lower than findings in the current study. One study further classified the potential ADEs and found those that would have had a serious impact on patient wellbeing to be 26% (Gandhi et al., 2005a). However, a true comparison with these studies and others in general medicine is problematic because tools for assessment of severity were not standardised. However, one study which modified the NCC MERP tool, similar to the current study, found that 60% of errors had the potential to cause serious/significant – life-threatening harm (Lisby et al., 2005). Nevertheless, Lisby and colleagues (2005) studied errors occurring in general medicine and in comparison, with the current study, differences in the patients' clinical conditions and the drugs used in treatment of cancer would be expected.

None of the published studies included a prediction of the potential clinical outcome in patients if pharmacists had not intervened to stop errors. Clearly, the disease is the most powerful predictor of patient outcome but patients with cancer are more likely to suffer iatrogenic injury caused by the inherent nature of the drugs used, or medication errors (Vincent et al., 1998). Findings from the current study revealed that prescribing errors have the potential to cause considerable impact on clinical outcome of patients. In many instances, the potential clinical sequelae of a prescribing error included a number of potential adverse events, mainly because cytotoxic chemotherapy is non-specific, affecting several organs at once (Ajani et al., 1990;Oken et al., 1982) .

The most common potential adverse outcome among errors was bone marrow suppression, leading to neutropenic sepsis, bleeding or anaemia (36.5%, n=80). Generally, patients with cancer who receive chemotherapy are four times more likely to develop bone marrow suppression when compared with those who are not exposed to these drugs (Nurgalieva et al., 2011). The risk of bone marrow suppression with chemotherapy is increased with the use of certain cytotoxic chemotherapy agents such as anthracylines (Du et al., 2002), which are among the most common drugs (17%) prescribed in the current study. Prescribing errors

can increase this risk further and may lead to preventable and unnecessary hospitalization. Nearly 5% of the errors identified in the current study had the potential to cause life-threatening complications, with one error having the potential to lead to death. For example, one patient involved in the potentially life-threatening error had advanced disease and presented with severe anaemia and severely impaired renal function. Although the use of end of life chemotherapy has been established and can lead to prolonging life and reducing pain (Simmonds, 2000), patients should be selected carefully. This is because in the presence of advanced morbidity and severe organ impairment, chemotherapy may, impair quality of life, increase suffering and hasten death (Prigerson et al., 2015).

Furthermore, focus group discussions revealed that patients suffered harm requiring prolonged hospitalisation and one patient died as a result of a prescribing error. The evidence for patient harm and death due to chemotherapy errors have been reported in the literature (Mehta et al., 1998). A review of the US Pharmacopeia Medication Error Reporting Program identified that 21% of patients died as a consequence of receiving the wrong medicine or the wrong dose. The article included an analysis of 40 incidents and reported that patients suffered permanent disability due to receiving an overdose of cytotoxic chemotherapy. Similar to findings from the current study, patient harm was associated with prescribing a higher than the intended dose or prescribing the chemotherapy over a longer period than that intended.

4.10.3 Classification of errors

The commonest errors identified in the current study were dose errors (34%) and evidence from focus group participants indicate that they have caused patient harm. Dose errors have been commonly reported in pervious prescribing error research in general medicine (Lewis et al., 2009) and cancer (Díaz-Carrasco et al., 2007;Gandhi et al., 2005b). The prescribing of cytotoxic chemotherapy involves the careful calculation of body surface area (BSA) or the use of specific equations such as the Calvert equation (Kaestner et al., 2007a). Dosage calculations that vary by more than 5% have the potential to be either sub-therapeutic or toxic (ASHP, 2002;NPSA, 2010b).

More than half of the dose errors in the current study were due to miscalculations. Calculation errors are commonly seen in medication safety research (Lesar, 1998) and in studies involving chemotherapy in adults (Bonnabry et al., 2006;Ranchon et al., 2012;Sano et al., 2005) and paediatrics (Rinke et al., 2007), leading to infection, impaired organ function and death (Fyhr et al., 2012). Analysis of 60 medication error incidents reported

to the Swedish national error reporting system identified that nearly half were dose errors and involved miscalculation of the BSA or misapplication of the Calvert equation (Fyhr et al., 2012). Interviewees in the current study admitted that they had difficulties calculating some doses, specifically carboplatin, and preferred to simply write the desired dosage range (expressed as Area Under the Curve) and allocated the task to pharmacists.

A statistically significant association between errors and prescribing cisplatin (chi-square test $p < 0.001$) or carboplatin (chi square test < 0.05) was identified, in the current study, and were mainly caused by inappropriate dose adjustments according to renal function. Both drugs are widely used in cancer chemotherapy (Tsang et al., 2009), however, their broad spectrum of activity means they can cause several ADRs, including; mucositis, bone marrow toxicity, nausea, vomiting and neuropathies (Miller et al., 2010). These drugs are entirely cleared by the kidneys and have the potential to cause, renal impairment and failure, with renal toxicity being dose limiting (Miller et al., 2010). Hence dose adjustment in renal impairment is imperative to ensure that patients do not suffer undue and prolonged ADRs (Kalyn et al., 2011). Both drugs have been reported in the literature to be associated with cytotoxic medication errors (Harris et al., 2005a). Furthermore, dose errors for patients with renal impairment accounted for 14% of prescribing errors in a Nigerian hospital (Ajemigbitse et al., 2013b). As found in the current study, the doctors interviewed admitted that they experienced difficulties when adjusting drug doses in renal impairment (Ajemigbitse et al., 2013b). This was also confirmed by findings from focus group in the current study, where doctors relied on pharmacy to calculate dose adjustments.

Pharmacists were able to identify and intercept three prescriptions which contained a tenfold overdose of three different drugs. Tenfold errors have been identified in other studies associated with chemotherapy (Fyhr et al., 2012) and general medicine (Lesar, 2002). A study of nearly 4000 prescriptions at a US hospital revealed that tenfold dose errors occurred with a frequency of 5% (Lesar, 2002). This is higher than the findings of the current study, mainly because of the different settings. Lesar (2002) studied adults, paediatrics and neonates, and described that tenfold errors were associated with misplacement of decimal points or where the dosage range was wide. In the current study, the tenfold errors were not due to misplacement of decimal points but addition of a zero to the dose. The considerable patient risk presented by the tenfold errors, in the current study, led to their classification as having the potential to cause life-threatening harm.

The second most commonly detected prescribing error type involved the prescribing of a contraindicated drug (28%), usually in a patient who had organ impairment that precluded

the use of chemotherapy. Medication errors caused by the use of a contraindicated drug are not common in prescribing error research, in western countries (Lewis et al., 2009). The use of a contraindicated drug was found to be 1% among prescriptions errors identified among junior doctors from eight hospitals in Scotland, relatively lower to findings from the current study (Ryan et al., 2014). However, research conducted in the EMRO region has reports of errors caused by prescribing of contraindicated drugs. In a study conducted in Bahrain among infants treated in 20 health centres, 16.1% in 5754 prescriptions contained a contraindicated drug that was not licensed for use in infants (Al Khaja et al., 2007). The authors of the study stated that published literature showed possible patient harm from use of these contraindicated drugs in infants but the potential or actual clinical harm was not reported (Al Khaja et al., 2007). In contrast, contraindicated prescriptions identified in this study had the potential to cause severe harm to patients. For example, the use of anthracyclines in patients who have exceeded the lifetime cumulative dose of these drugs (450-900mg/m^2) can lead to considerable cardiac toxicity (Kalyn et al., 2011). In the current study, this was identified in 2% of prescriptions with errors. Cancer and chemotherapy guidelines specify clearly that patients' blood parameters and, where relevant, liver, renal and cardiac function, should be monitored, before initiating chemotherapy treatment and before each cycle of treatment (ASHP, 2002;Kalyn et al., 2011;NPSA, 2010b). Monitoring is essential to ensure that patients can tolerate treatment and to reduce the severity of ADRs. Each chemotherapy treatment protocol has clear limits for these parameters, below which the treatment is contraindicated, and may need to be delayed or stopped (Reed, 2008).

Other common errors identified in the current study were scheduling errors (11%) and inaccurate length of therapy (10%). Scheduling errors were the least common error identified in comparable medication research (Nerich et al., 2010). They are akin to frequency errors which have been reported in prescribing error research carried out in general medicine in both high income countries (Lewis et al., 2009) and countries from the developing world (Agalu et al., 2011;Al-Dhawailie, 2011;Al-Jeraisy et al., 2011) . The importance of scheduling chemotherapy doses every 14-21 days is based on bone marrow recovery after use of these drugs (Skeel et al., 2007) Variations in chemotherapy intervals by up to 3 days is permitted within some protocols (Williamson, 2010), however, when chemotherapy is prescribed outside these variations, the possible impact on patients' health may be severe. This was demonstrated in this study, where all prescriptions prescribed out of schedule, but one, had the potential to cause serious/significant harm to patients.

4.10.4 Causes of prescribing errors

Reason's (1990) model of accident causation allowed a detailed analysis of the types of active failures discussed in the critical incident interviews. The errors were further analysed to identify latent causes and error-provoking conditions using Vincent's (1998) adaptation of Reason's error causation model (1990). As a result, active failures were associated with a number of interlinked error-provoking conditions which were influenced by several common latent managerial and organizational factors.

4.10.5 Types of active failures

The ten errors (active failures) included in the critical incident interviews were caused by slips, knowledge based mistakes or rule based mistakes and violations. The findings indicated that slips and violations were more common than mistakes. Comparison with work conducted in chemotherapy, or with medication errors in developing countries in similar settings such as the countries of AFRO/EMRO regions, is difficult because none of the published studies used this particular framework for error analysis. However, when compared with findings published in a review of research conducted mainly in the UK, US and Canada, the results were interesting (Tully et al., 2009). The commonest types of active failures reported in the review undertaken by Tully et al (2009) were mistakes and violations were less common. This may be explained by difference in the grade of prescriber involved, where the hospitals included in the review were mostly general medicine hospitals where junior doctors were likely to be responsible for most of the prescribing and hence are more likely to have little knowledge about the drugs they prescribe (Coombes et al., 2008). In comparison, with the cancer hospital under study, all prescribers are either fully qualified doctors or registrars undergoing further specialist training.

The violations identified in this study were due to both routine violations and exceptional violations. Errors caused by violations have been reported elsewhere, and occurred in the current study because of conscious decisions by the prescriber to ignore written protocols, informal rules and common sense or professional responsibility. All four errors identified due to violations had the potential to cause significant harm in patients. Routine violations occurred when doctors failed to confirm or carry out essential routine monitoring required for cancer chemotherapy. Doctors confirmed this finding during focus group exercises where they attributed violations to failure in monitoring patients before prescribing chemotherapy, resulting in patient harm. Reports of failure in therapeutic monitoring have

been published in prescribing error research conducted in the EMRO region of the WHO (Al-Hajje et al., 2012). One fifth of prescriptions with errors in a Lebanese hospital were prescribed without ordering the appropriate monitoring, leading to one patient suffering harm (Al-Hajje et al., 2012). Monitoring patients before and during cytotoxic chemotherapy is an essential requirement (Reed, 2008). Both doctors involved in the errors stated that they were aware that this was a requirement written in the chemotherapy protocols at the study hospital but admitted that they routinely failed to check certain laboratory values before prescribing chemotherapy. Protocols in chemotherapy are important to standardize practice and improve patient outcomes (ASHP, 2002). However, doctors have been reported to deviate from clinical practice guidelines and treatment protocols (Oxman et al., 1995). In Sudan doctors commonly deviate from national and WHO treatment protocols for management of childhood infections, leading to unnecessary prescribing of antibiotics and in other events treatment failure (Elfaki, 2009;Salih et al., 2014;Taha et al., 2014). Many possible causes for these deviations have been reported, including inadequate guideline implementation (Oxman et al., 1995) and doctors' attitudes and beliefs (Wahabi et al., 2012).

4.10.6 Error-provoking conditions and latent factors

The active failures identified in this study occurred because a number of latent errors combined with error provoking conditions to provide the necessary environment for prescribing errors.

4.10.6.1 Latent factors

In the current study, the most common latent factors causing errors was clinic organization, culture, and lack of training and procedures.

The effect of clinic organization on errors has not been previously reported in medical error research (Dornan et al., 2009;Tully et al., 2009). However, a number of errors included in the critical incident interviews took place in 'makeshift' clinics, where doctors reviewed patients and prescribed chemotherapy in doctors' offices or the doctors' tea room. Doctors' accounts identified that these areas lacked essential elements necessary for smooth running of an outpatient clinic such as ancillary staff, adequate access to medical records and equipment necessary for calculation of chemotherapy dosing. Furthermore, clinic inadequacies were not limited to these 'makeshift' clinics but were also present in the official outpatient clinic. During interviews, doctors expressed frustration with the design of

clinics and attributed error to damaged and deficient equipment. These views were also expressed during the focus group discussions, where doctors felt that poor clinic organization contributed to errors. Poor design of treatment areas, clinics and medicine storage areas is common in Sudanese hospitals where financial resources are generally limited (Cheraghali et al., 2009). A study conducted in a number of hospitals in the capital Khartoum, showed that more than 40% of drug storage facilities were poorly equipped for purpose (Cheraghali et al., 2009).

The second most common latent condition involved in error causation was culture, where junior members of staff were not able to question senior members of the team. A culture of speaking up and reporting areas of concern is an important factor in establishing a patient safety culture, in both industry and healthcare (Blegen et al., 2010;Sexton et al., 2006 ;Sexton et al., 2000) . In contrast, a culture where junior doctors are unable to question their superiors has been directly linked to prescribing errors and risk to patient safety (Dean et al., 2002a;Tully et al., 2009).

During both critical incident interviews and focus group discussions, the doctors admitted there were occasions where they had safety concerns when writing a prescription. However, they proceeded on direct orders from a senior member of staff and were either too afraid to speak up or were reproached when they raised concerns. On all occasions, the doctors disclosed that such situations were common but they felt obliged to obey orders without question. Such attitudes were regarded as intimidation among junior doctors in a Nigerian general medicine hospital (Ajemigbitse et al., 2013b). Intimidation towards junior staff may be regarded as an element of disruptive behaviour, an issue which is known to contribute to a poor safety culture where errors are not intercepted (Leape et al., 2012) and has been reported in both studies from high income countries (Rosenstein et al., 2008) and developing countries (Ogunsemi et al., 2010). Leape (2012) explained that disruptive behaviour affects patient safety because it has both short term and long term implications. In the short term, it can contribute to low morale, anger and frustration, sentiments that were expressed by one interviewee in the current study. Furthermore, it influences the person's ability to think clearly, thus contributing to errors when performing tasks. This was demonstrated in the current study where two doctors wrote prescriptions as a response to direct orders from an intimidating senior consultant, each leading to a tenfold dose error. In the long term this type of behaviour may lead to loss of communication, poor teamwork relationships, patient dissatisfaction and errors (Rosenstein et al., 2008).

Two common managerial latent factors identified were lack of procedures and lack of training. During focus group discussions and the critical incident interviews, doctors stated that they were new to the centre and were asked to start prescribing chemotherapy but were unaware of existing procedures and prescribing processes. Lack of training has been associated with prescribing errors in previous research in general medicines in countries of high income (Coombes et al., 2008;Dornan et al., 2009;Tully et al., 2009) and in AFRO countries (Ajemigbitse et al., 2013a;Awad et al., 2007). It has also been identified as a cause in chemotherapy-associated adverse events (Mehta et al., 1998).Training in general is essential for reducing prescribing errors (Celebi et al., 2009) improving quality control of processes (Woodman et al., 1996) and is a component of organizational cultures that foster patient safety(Singer et al., 2009a). It is a key requirement for prescribing of chemotherapy, and should be the responsibility of both management and the individual HCW (NPSA, 2010b). Chemotherapy guidelines state that doctors should be offered training at induction, with a requirement for regular updating and maintenance of relevant records to ensure ongoing competence (NPSA, 2010b). Furthermore, the implementation and dissemination of SOPs are necessary to ensure standardization of practice (Gilmore et al., 1998) and essential for reduction of chemotherapy errors (Muller, 2003).

4.10.6.2 Error-provoking conditions

In the presence of latent factors and weak defences, a number of error-provoking conditions contributed to errors. These were categorised into the individual prescriber, their work environment, the broader healthcare team, the prescribing task and the patient. The findings of this study confirm reports from other prescribing error studies that multiple error-provoking conditions contribute to errors and are sometimes common to a number of errors (Coombes et al., 2008;Tully et al., 2009).

Errors related to the task were most the most commonly identified, in the current study. For example, handwritten prescriptions contributed to a number of identified errors in this study. The findings from the current study showed that nearly a quarter of prescriptions had various omissions, either the name or other essential prescriptions details were missing. Similarly, previous chemotherapy error research has shown that handwritten prescriptions contained a number of errors (Ford et al., 2006;Oberoi et al., 2014;Slama et al., 2005), were higher in comparison with computerized prescriptions (Huertas Fernandez et al., 2006) and were mainly associated with omissions (Mathaiyan et al., 2015). A study conducted in a developing country (North Indian region), where chemotherapy

prescriptions were handwritten, identified that 7.4% (total sample 289) contained an error (Oberoi et al., 2014). Although Oberoi and colleagues (2014) studied oral chemotherapy prescriptions, their research confirmed that handwriting of chemotherapy prescription is a complex task and may be a contributory cause of errors because doctors are likely to forget doses, supportive therapy and instructions for administration (ASHP, 2002;Dinning, 2005).

Patient factors also contributed to errors in the current study. Doctors felt that they were obliged to meet patients' demands and hence might issue a prescription that did not meet the necessary pre-requisites, or prescribe chemotherapy when not indicated. For example, a doctor prescribed chemotherapy for a patient without reviewing pre-treatment laboratory investigations. The effect of patient demands on prescribing decisions was reported in Sudan (Yousif et al., 2011). A questionnaire survey among 155 doctors working in primary care centres showed that over half (52.5%) prescribed unnecessary drugs under patient demands (Yousif et al., 2011). Studies have shown that patient demand is a recognised and important contributor to the prescribing decision (Bradley, 1991) and has contributed to irrational prescribing of antibiotics (Radyowijati et al., 2003). It has been recognised that training is essential to enable prescribers to manage unreasonable patient demand (Barber, 1995).

Active failures identified in the current study were also associated with the individual prescriber. In three incidents, doctors appeared to show poor professional responsibility and have a casual attitude to the prescribing task, similar to that identified previously (Coombes et al., 2008). Similar to published prescribing error literature, doctors in the current study attributed errors to stress, and inability to ask questions (Tully et al., 2009).

In the broader team context, new doctors at the study hospital often prescribed chemotherapy under inadequate supervision. Furthermore, failures in communication with both senior members of the team and other colleagues were common. Team work and effective communication have been highlighted as important factors in establishing a culture of safety (Sexton et al., 2000). Team work failures have been identified in previous medical research (Sexton et al., 2000),and were found to have a considerable impact on patient safety in low-income countries (Aveling et al., 2015), highlighting an assumption that human factors are likely to be shared across cultures.

Although the current study highlighted that organizational factors were responsible for creating an inadequate work environment, where hectic conditions were common. This was

confirmed in the doctors' accounts where, similar to finding from previous research, doctors in the current study attributed errors to busy work environments and interruptions.

4.10.7 System defences

In the presence of human factors, systems function because defences are placed to prevent, intercept and mitigate errors (Reason, 1997). In the absence of procedures, induction training, and in a poorly designed work environment, participants in the current study revealed that they relied on pharmacists to identify and intercept prescribing errors. Cancer chemotherapy guidelines recommended that prescriptions should be verified by both pharmacists and nurses, to ensure errors are identified before reaching patients (Cohen et al., 1996). Generally, the inclusion of pharmacists in medical teams had a positive effect on reducing the incidence and severity of errors (Palmer, 2013). Furthermore, evidence has shown that junior doctors, in particular, relied on pharmacists to correct their doses and felt safe that errors would be intercepted before reaching patients (Dornan et al., 2009).

However, the efforts of pharmacists in intervening to rectify errors would be partly effective because, in the absence of an error reporting system, learning from errors might not take place and errors may be repeated and may lead to harm (Reason, 1997). Evidence from doctors' accounts during the current study have indicated the prescribing errors repeatedly occur and have resulted in harm. Reporting of errors is essential to patient safety and has been recommended as an important safety measure when using chemotherapy (Harris et al., 2005b). Feedback from such errors is useful to inform and tailor standard operating procedures, specific to each healthcare setting, and to ensure chemotherapy prescribing is standardised and delivered in a safe manner (Harris et al., 2005b) .

A number of other interventions shown to reduce prescribing errors associated with chemotherapy include the use of pre-printed prescription templates (Dinning, 2005) and computerized prescribing (Voeffray et al., 2006). The effect of pre-printed prescription templates has been demonstrated when these were introduced in a US cancer centre, leading to the removal of prescribing errors (5% to 0%) (Dinning, 2005). The use of standardised prescription templates in the current settings, has the potential to reduce errors. They may potentially reduce nearly a quarter of errors associated with the omissions of drug, drug doses and prescription details.

Additional benefits can be achieved through CPOE, a well-known intervention for reducing medication error generally (Bates et al., 1999b). The introduction of CDSS has added more

benefit because it was designed to provide decision support features (Gandhi et al., 2005b). In a US based 700 bed cancer hospital, implementation of a CPOE, with CDSS, resulted in a significant reduction of prescribing errors (Elsaid et al., 2013).The authors revealed that prescribing errors before the implementation of computerized prescribing were 17.8 errors per 1000 doses which was reduced to 7.9 errors per 1000 chemotherapy doses (Elsaid et al., 2013).More importantly, such systems have in-built alarms which would alert the prescriber to higher than usual doses and prevent tenfold doses (Nerich et al., 2010).

However, there are a number of disadvantages to the use of CPOE, such as the requirement for intensive training and additionally, error cannot be entirely eliminated (Small et al., 2008). In the US, as part of a quality improvement initiative, changes to the prescribing systems at a cancer hospital were made gradually, first by introduction of pre-printed prescription templates and then by introduction of CPOE (Meisenberg et al., 2014). The authors appointed a pharmacist to review every 10th chemotherapy prescription against national prescribing standards. Prescriptions were reviewed for a 12-month period, before introduction of pre-printed prescriptions, after introduction of pre-printed prescriptions and after introduction of CPOE. A total of more than 10,000 chemotherapy prescriptions were reviewed and the error rate was 4.2% with handwritten prescriptions, 1.5% with pre-printed prescriptions and 0.1% with CPOE. The use of pre-printed prescriptions resulted in elimination of some prescribing errors associated with drug name legibility, abbreviation of drug names, confusion of dosage units, omission and duplication errors. In addition, computerized prescribing eliminated errors in patient details entry, dose calculations and dose adjustments according to renal function. However, it was shown that changes made to the CPOE by doctors which were meant for one chemotherapy cycle may inadvertently continue, resulting in either unintended dose escalations or dose reductions (Meisenberg et al., 2014).

4.10.8 Limitations of the current study

The current study has several limitations. The study design was intended to be process based rather than outcome based and hence patient harm was not identified. However, identification of medication errors which have the potential to cause ADEs is valuable in identifying gaps in the safety of medical services (Gandhi et al., 2000;Morimoto et al., 2004). Furthermore, The use of centralized pharmacist screening of prescriptions has a number of limitations, primarily the variation in clinical skill amongst pharmacists, some errors may go unnoticed and lastly that pharmacists based in the pharmacy have no access to patients and

hence are likely to have limitations in evaluating the clinical condition of the patient fully (Lewis et al., 2009). However, in the current study, to ensure minimal variations associated with individual pharmacists' prescription screening skills, all those involved during data collection underwent standardized training and assessment before the study began. Moreover, it is unlikely that a significant number of errors would have been overlooked using this method because previous prescribing error research had shown that the vast majority of errors are intercepted in the pharmacy (Dornan et al., 2009). In general, prescription screening by pharmacists has been shown to be more effective when conducted on wards rather than in the dispensary where there is no access to patients' notes and other information gained from the medical and nursing teams (Tully et al., 2009). However, in the current setting, the chemotherapy prescription was sent to the pharmacy accompanied with the patient's notes. Hence pharmacists were in a better position to make sound clinical judgements because they were able to review the patient's medical records and laboratory investigations. Consequently, relative to traditional dispensary prescription screening, the pharmacists in the current setting may be more capable of identifying errors. The measure of severity used in the current study was based on a scale used to assess actual harm rather than predict potential harm. The NCC MERP scale was used by a number of other prescribing error studies and found to have good reliability and validity when compared with other scales (Garfield et al., 2013)

One important limitation of this study was the relatively small number of doctors involved in the critical incident interviews, in comparison with the total number of doctors associated with prescribing errors. The working patterns of the doctors at the study meant that most interviews could only be conducted 96 hours, after the prescribing error, which would have affected recall and introduced bias into the study. In order to involve more doctors in the current study, focus groups were arranged with three prescriber grades. Findings from both groups were consistent and doctors in focus group discussions were able to recall incidents where patients have been harmed. Furthermore, the themes which emerged from analysis of both studies were common among most of the participants, which contributed to confirmation of the contributory causes of errors.

4.11 Conclusions

In the current study the prescribing error rate was found to 10%, the majority (78%) of which had the potential to cause serious harm to patients and 10% had the potential to be life-threatening. Furthermore, findings from focus group discussions identified that patients

have been harmed as a consequence of prescribing errors. These are serious findings which could lead to significant numbers of patients being harmed unless the situation changes. Most errors were caused because the prescriber had miscalculated doses or had not carried out the necessary patient monitoring before writing the prescription. Interviewees suggested that the practice of not regularly monitoring patients was common and chemotherapy prescription writing was not given due importance. There was a culture of submissive behaviour in the centre, where junior doctors wrote prescriptions knowing that they were wrong but did so because they felt intimidated by their superiors. Senior members of staff routinely ignored best practice when prescribing chemotherapy. Other factors involved in errors were a lack of training for new doctors, lack of procedures and poor organization of clinics. In the study hospital, doctors relied extensively on pharmacists to intercept errors and rectify prescription deficits.

There has been a noticeable increase in patients presenting with cancer over the last decade in Sudan (Saeed et al., 2014). Although the use of chemotherapy is supported by well documented clinical trial evidence, which has shown improved quality of life and survival with chemotherapy, substantial harm to patients can occur (Nurgalieva et al., 2009). Due to the inherent risks associated with the use of chemotherapy, healthcare institutions where these drugs are used should have the necessary support in terms of human resources, infrastructure and drugs (Anderson et al., 2008). These drugs are now available on the EML of low income countries (WHO, 2007a) and should be prescribed in environments that are carefully tailored to optimise patient safety (WHO, 2008b).

In the light of the findings from the current study, further research is required to identify the impact of errors on patients and how adverse events are managed.

CHAPTER FIVE

5 FREQUENCY, TYPES AND CAUSES OF CHEMOTHERAPY PREPARATION AND ADMINISTRATION ERRORS

5.1 Introduction

The WHO predicts a 50% increase in the number of cancer patients by 2020, mostly in developing countries such as Sudan (WHO, 2005c). This has been reflected in the extensive list of cytotoxic chemotherapy agents included in the most recent WHO list of Essential Medicines (WHO, 2007a). A continued rise in the use of these cytotoxic agents in healthcare is expected, which, given the toxicity profile of many of these agents, may increase the risk of adverse consequences among cancer patients. Furthermore, the International Agency for Research in Cancer (IARC) has classified 30 cytotoxics as carcinogens or possible carcinogens (IARC, 2012). Handling these agents in unprotected environments is associated with ill health effects (Dranitsaris et al., 2005), as a number have been classified as irritants (Allwood et al., 2002) and many have long term effects such as teratogenicity (Briggs et al., 2011).

5.1.1 The effect of occupational exposure to cytotoxic chemotherapy

When cytotoxics are prepared in areas without appropriate ventilation, these agents can be detected in the air and the environment (deWerk et al., 1983). It is thought that these agents enter the systemic circulation of nurses through accidental ingestion, aerosol inhalation (Hirst et al., 1984) and via dermal transfer (Fransman et al., 2004;Bos et al., 1997). For example, significant amounts of the cytotoxic cyclophosphamide were detected by swab testing of the hands, forearms and foreheads of nurses preparing these drugs and handling patients' excreta (Fransman et al., 2004). This is not surprising because work surfaces are often contaminated (Fransman et al., 2004;Connor et al., 1999;McDevitt et al., 1993) even in areas far from the handling site (McDevitt et al., 1993) and significant amounts of these drugs are excreted in patient's urine (Falck et al., 1979) and faeces (Yuki et al., 2013). It is feasible that these drugs have the potential to harm personnel exposed to them. Unfortunately, the evidence on actual harm in HCWs is contradictory and scanty, and is based on data from nearly 40 years ago, at a time when guidelines for personal protection where not yet established (Anderson et al., 1983).

The mutagenic effects of these agents have been confirmed in a number of studies (Anderson et al., 1982;Falck et al., 1979). The first evidence documenting that nurses were exposed to cytotoxics was provided by Falck and colleagues (1979). They collected urine samples from nurses and patients exposed to cytotoxic chemotherapy , nurses who had just completed a weekend break and other staff who were not handling these drugs (Falck et al., 1979). The urine samples of the four groups were tested for potential to induce

mutagenicity on *Escherichia Coli and Salmonella Typhimurium* species. Unsurprisingly, mutagenicity was found to be dose dependent, being higher in patients who had received cytotoxic chemotherapy , lower in nurses occupationally exposed to these drugs and very much lower in nurses after a duty free weekend and non-existent in personnel not directly handling cytotoxics (Falck et al., 1979). This finding has been confirmed by others (Sessink et al., 1994;Anwar et al., 1994). Patients who received chemotherapy had a seven-fold risk of developing secondary haematological malignancies (Rosner et al., 1978). More recently a study confirmed these findings in a 9-year follow up study of a cohort of 1,545 women who received chemotherapy for the management of breast cancer (Crump et al., 2003). Ten of these women developed secondary leukaemias, thought to be caused by anthracycline-induced chromosomal aberrations (Crump et al., 2003). Lassila and colleagues (1980) argued that this effect may not have direct health consequences on nurses exposed to the drug, because in their study there was no evidence of the immediate effects on the immune system (Lassila et al., 1980). However, the authors of this study did not consider that substantially higher blood concentrations of these drugs are required to affect the immune system. Nonetheless, the evidence of documented carcinogenicity of these agents is substantial and their effect on exposed personnel warrants special consideration.

A number of studies conducted to examine the effects of handling cytotoxic chemotherapy on the unborn foetus of pregnant women revealed some evidence of teratogenicity. A case control study conducted among 650 nurses preparing and administering cytotoxic chemotherapy in 17 Finnish hospitals found a significant association between foetal loss and exposure to these agents (Selevan et al., 1985). Further studies revealed spontaneous abortions (Dranitsaris et al., 2005) and infertility (Martin, 2005) and a possible effect on the germ line (Valanis et al., 1999). A review of 14 studies conducted across western countries, examining the health effects due to occupational exposure to cytotoxics, found that significant exposure to these drugs when a nurse is pregnant does have the potential to pose a health risk to the unborn foetus, principally spontaneous abortion (Dranitsaris et al., 2005).

5.1.2 Protection from occupational exposure to cytotoxics

This body of evidence prompted health and safety agencies around the world to develop guidelines for handling and safe disposal of cytotoxics. The Control of Substances Hazardous to Health (COSHH) guidelines were published in 1988 by the UK Health and Safety Executive and have been updated to provide new guidance specific to handling of cytotoxics (HSE,

2003). These, as well as other guidelines, require that workplace risk assessments are conducted to identify substances which are hazardous to health and hence provide protection to employees. Guidelines were developed by the governments of the US, UK, Ireland, Denmark, Germany, Finland, Sweden and Australia, as well as the European Community and the WHO (Carrington et al., 2010b;Jacobson et al., 2009;Allwood et al., 2002;HSE, 2003;Frontiers et al., 1999). Some of these guidelines provide detailed advice on the requirements when dealing with cytotoxics during transport, storage (ISOPP, 2007a) prescribing (NPSA, 2010b), dispensing, preparation (ISOPP, 2007a), administration, monitoring of patients (Jacobson et al., 2009) and disposal of waste (Frontiers et al., 1999).

A European Directive specifies the three levels of hierarchical protection against cytotoxic agents (ISOPP, 2007a):

1- Substitution with less toxic drugs
2- Containment of the toxic drug
3- Use of engineering and technology via biological safety cabinets and ventilation to reduce risk of exposure

Since substituting cytotoxic chemotherapy with less toxic drugs is currently not feasible, the second and third hierarchical levels of protection have been recommended (ISOPP, 2007a). These agents should only be handled while wearing PPE which includes gloves, gowns and eye protection for everyone preparing or administering these drugs and the use of specialised masks for use when cleaning cytotoxic spills and dealing with powdered drug formulations (Allwood et al., 2002). In addition, routine preparation of cytotoxics should be carried out in a centralized pharmacy under a High Efficiency Particulate Air filter (HEPA) filtered vertical laminar flow isolator or cabinet by HCWs who are trained and whose aseptic technique is regularly assessed (NPSA, 2010b). These guidelines have become legislation in some countries where non-adherent employers run the risk of legal action (Eisenberg, 2012;HSE, 2003;HSE, 2002). The guidelines are certainly an important safety measure ensuring HCW protection while handling cytotoxics.

Advances in the technology of preparing cytotoxics have evolved during the last decades and have certainly reduced occupational exposure. Worldwide, the preparation of cytotoxics on wards has been largely abandoned by most cancer hospitals, to become a centralized pharmacy service. Early work has shown that centralization of cytotoxic chemotherapy reconstitution has resulted in a number of improvements to previous practice, principally improvements to safety of both patients and nurses and a decrease in

cytotoxic waste (Anderson et al., 1983). Preparation in pharmacy departments is mainly conducted within the confines of ventilated biological safety cabinets which operate under vertical laminar flow (Allwood et al., 2002). Isolator technology provides further reduction to both personal exposure and surface contamination (Crauste-Manciet et al., 2005). Surface contamination is not easy to eliminate because spills are likely during manipulation of intravenous medicines, using needles (Crauste-Manciet et al., 2005). Furthermore, certain cytotoxics such as cyclophosphamide can vaporise (Connor et al., 2002) and the surface of vials are often contaminated when delivered to the pharmacy (Sessink et al., 2011). The use of closed systems has emerged to reduce spills during manipulations, and reduce vapourisation of drugs (Allwood et al., 2002). Closed system devices are drug transfer devices that are designed to mechanically stop the transfer of liquids or gases to the outer environment of a drug vial and do not allow contamination to enter vials (Yoshida et al., 2009). The combined use of closed system devices and biological safety cabinets have demonstrated a much lower reduction in the level of surface contamination and absorption of cytotoxics by personnel (Connor et al., 2002). Connor and colleagues (2002) collected wipe samples of ifosfamide from the surfaces of a pharmacy where nearly 20g of the drug were prepared daily. Analysis of the wipes showed that surface contamination has been reduced by at least 3 times the level previous to introduction of the closed system method. The finding that occupational exposure cannot be eliminated was also confirmed by Wick and colleagues (2003). Nevertheless, these technological advances do substantially reduce occupational exposure to cytotoxics and have been recommended to be used during compounding of cytotoxics by international oncology bodies (ISOPP, 2007a).

The implementation of these guidelines should greatly reduce occupational exposure to cytotoxics. However, there is still evidence of teratogenicity from the literature. The evidence of spontaneous abortion secondary to chemotherapy exposure was provided by a systematic review conducted by an expert panel for Cancer Care Ontario (Green et al., 2009). The authors reviewed 16 studies that examined the pregnancy outcomes of HCWs occupationally exposed to cytotoxics before 1985 and after 1985 and found that the risk of spontaneous abortion was still evident although less than before implementation of the legislation but no conclusive evidence was found of these drugs causing malformations in children born to these mothers.

The benefits of using cytotoxic chemotherapy in patients outweigh their extensive risks but HCWs are at risk from continuous low levels of exposure. Since no single method has been shown to confer complete protection against occupational exposure to these drugs, care

and diligence must be exercised by both HCWs and employers to ensure minimal occupational exposure to these agents. Guidelines from the Health and Safety Executive (HSE) England specify that since a safe level of exposure to cytotoxic chemotherapy is not possible, pregnant mothers should either completely avoid exposure or reduce it to the lowest practical level (HSE, 2002). It is, hence, without doubt that occupational exposure to these drugs should be reduced in HCWs, more specifically those who are pregnant or planning a pregnancy. Handling of these agents should be limited to personnel who have been given the correct training (ISOPP, 2007a), ideally to certification level (Fischer et al., 1996) and their competence regularly assessed (NPSA, 2010b). Preparation of cytotoxics should be limited to pharmacies under appropriate environment and preparation in clinical areas should be minimised (ISOPP, 2007a;NPSA, 2010b). Guidelines have been developed by a number of western countries to ensure safety to both operators and patients (Green et al., 2009), and more specifically targeting the reduction of occupational exposure and ADEs (Jacobson et al., 2009). One example is reducing the vesicant effect of cytotoxics. A large number of cytotoxics are vesicant or irritant (Allwood et al., 2002) and sequencing of administration is important to ensure that a neutral agent is injected into the patient's vein before completion of the administration process. Because of their vesicant properties, these drugs can cause substantial damage to the area around the administration site if they extravasate (Bertelli, 1995). Hence, nurses should have the necessary training and skills required to reduce the incidence of extravasation and manage patients appropriately if this occurs.

The importance of personal diligence cannot be underestimated and HCWs should take the responsibility of adhering to guidelines and following standard practice and procedures during the preparation and administration of cytotoxic chemotherapy.

5.1.3 Administration errors involving intravenous administration of cytotoxic chemotherapy

The administration of medicines in many countries is regulated by standards and legal directives. Central to these standards are the five rights of medication administration; right medicine, right dose, right patient, right route, right time (Westbrook et al., 2010). A number of authors proposed seven and nine rights of medication, adding verification of medication, documentation, use of aseptic technique during preparation and review of patients after completion (Crimlisk et al., 2009;Pape, 2003).

Equally important to patients' receiving the right medication, Michelle Cook, a US nurse, argues that there are six rights that nurses should be afforded to execute the process appropriately (Cook, 2006). These are :1) the right to a complete and clearly written prescription, 2) The right to have the correct drug dispensed, 3) the right of access to drug information, 4) The right to have clearly written policies and procedures for medication administration, 5) The right to administer medicines in a safe setting and where they can identify weaknesses in the system and lastly 6) the right to stop, think and be vigilant when administering medicines (Cook, 2006). These rights ensure that nurses have the appropriate environment and tools to administer medicines safely.

Nurses are historically known to be the main HCW involved in the administration of medication in hospitals and can also be to varying extent involved in the dispensing of medicines, such as crushing tablets and drawing up injections (Hughes et al., 2008). There is evidence of administration errors where HCWs other than nurses have been involved (Wirtz et al., 2003), but most reported errors have involved nurses (Phillips et al., 2001).

Much of the evidence available regarding the incidence, nature and causes of administration errors is from early work regarding patient safety in western countries. Early medication error research has shown that one third of medication errors that resulted in patient harm were caused by an administration error (Barker et al., 2002b;Leape et al., 1995). The common reasons for administration errors that led to fatalities were wrong drug, wrong dose and wrong route (Phillips et al., 2001).

In one of the largest observation studies, Barker and colleagues (2002) investigated administration errors in 36 health care facilities from two states in the US. They observed 3,216 doses prepared and administered by nurses, of which 19% contained an error, mostly wrong time errors. Others were omission errors, wrong dose and administration of a drug that was not prescribed (Barker et al., 2002b).

Medication administration errors occurred more commonly when administering bolus injections or drugs that require multiple steps during administration (Taxis et al., 2003b). In their study, Taxis and Barber (2003) observed the preparation and administration of 430 intravenous doses in ten wards from two UK hospitals. Almost half of all the doses were associated with at least one preparation or administration error, a rate much higher than the US study (Barker et al., 2002a). A higher rate of errors was found in another European multi-centre study that collected data from Germany, France and the UK (Cousins et al., 2005). The authors observed the preparation and administration of nearly 700 intravenous

doses from six departments from the three countries. Rates of error differed by country, where, 49% of doses were either not labelled or labelled incorrectly, in UK hospitals. Unlike Barker et al's (2002) findings, the most common administration error was giving the drug either too quickly or too slowly. Major deviations in aseptic technique were also reported because nurses in the UK hospitals under study never wiped the surface preparation surface or washed hands before starting the preparation of intravenous medicines. Similar deviations in aseptic technique were observed in UK based paediatric hospitals (Ghaleb et al., 2010). Ghaleb and colleagues (2010) observed 161 nurses administering over 1500 doses across five paediatric hospitals in the UK. The medication administration error rate was 19.1%, the commonest being preparation errors (20.7%), followed by wrong rate of administration (19.8%) and dosing errors (9.3%). A review of ten studies conducted in western countries revealed that the most common type of error was during reconstitution of intravenous drugs, contributing to nearly 21% of all preparation and administration errors (McDowell et al., 2010). A number of reasons were attributed to the cause of these errors, including poor training, poor labelling of medicines, inadequate medicine storage facilities, insufficient staffing levels, fatigue and distractions (McDowell et al., 2010). One of the main sources of distractions in western studies were interruptions. An observational study involving the preparation and administration of more than 4000 doses in two Australian hospitals revealed that preparation errors increase by 12% in the presence of interruptions (Westbrook et al., 2010).

Although published research is limited in the EMRO/AFRO region, intravenous medicine preparation and administration errors are common. A survey of 779 nurses across 22 Jordanian hospitals revealed that each nurse was aware that they were personally responsible for an average of 2.2 errors. Nurses attributed errors to poor labelling of medicinal products, confusion over the use of infusion devices and distractions (Mrayyan et al., 2007). Unlike reports from western countries (McDowell et al., 2010), preparation errors (33.4%) were less common than administration errors (66.4%). An observational study, conducted in an ICU unit in Iran, which involved 500 medication administrations, reported that 9.4% errors occurred among 4040 opportunities for error (Fahimi et al., 2008). Similarities to western studies were reported in the type of administration errors where bolus (Barker et al., 2002b) injections contributed 43.4% to total error rates.

Little work has been done to identify the magnitude of administration errors associated with cytotoxic chemotherapy. However, these errors tend to be more serious and common, occurring in most workplaces (Schulmeister, 1999). They are specified as a 'never event' in

the NRLS Framework (NPSA, 2010a). 'Never events' are medical incidents that are preventable and can cause serious harm to patients (NPSA, 2010a). A survey of 1240 US based Oncology Nursing Society nurses revealed that a cytotoxic drug error occurred in 63% of workplaces, mostly involving the administration of drugs. Another survey confirmed this finding and revealed that nearly half (41%) of all errors involving cytotoxic chemotherapy in a community oncology hospital in the US were associated with the administration of the drug (Ford et al., 2006). An analysis of the MEDMARX database in the US revealed that 43% of errors associated with chemotherapy were due to errors in the administration. However, the authors reported administration errors occurring in paediatrics with oral, intravenous routes and other routes (Rinke et al., 2007).

Handling of cytotoxics can be a source of risk to both HCWs and patients. Although very few studies were identified in the literature, focused on identifying and exploring intravenous cytotoxic chemotherapy administration errors, the available reports show they are common.

5.2 Aims and objectives

The overall aim of this study was to identify the incidence, nature and potential causes of medication errors during the chemotherapy administration process at a cancer hospital in Sudan.

Objectives:

- To describe the systems used to prepare and administer chemotherapy to patients attending a cancer hospital within Sudan
- To design and implement a system to capture medication errors made during the preparation and administration of chemotherapy
- To classify the preparation and administration errors detected
- To describe and analyse the potential causes of both preparation and administration errors

Traditionally, medication error research has been conducted using retrospective review of medical records (Baker et al., 2004;Bates, 1999;Bates et al., 1995b;Brennan et al., 2004;Classen et al., 1997;Cullen et al., 1997;Gandhi et al., 2003;Gawande et al., 1999;Leape et al., 1991;Vincent et al., 2001). However, researchers conducting the Africa and Eastern

Mediterranean Adverse Events study, a study directed by the WHO and in which Sudan participated, reported incompleteness of medical records (Wilson et al., 2012). These countries are classified as data poor because of incomplete record keeping and hence research utilizing record review would produce deficient results. The WHO have recommended that other methods would be more robust in these situations; such as observational research and prospective review of the records (WHO, 2010). Consequently, this study adopted a prospective mixed methods approach using observations and the critical incident technique. The purpose of the mixed method design was to both quantify and characterise the types of errors and also to gain a perspective of nurses' experiences when errors occur and their views about the cause of these errors.

The following section explains how the methods were developed and conducted to achieve the specific objectives, listed above.

5.3 Study design and methods

This project was conducted in three interlinked stages (see Figure 5-1):

Stage One- An exploratory study using key informant interviews with the aim of describing the workflow in the chemotherapy day ward. Findings informed the development of a data collection tool used in stage two.

Stage Two- An observation study to classify the types and frequency of medication errors occurring during preparation and administration of chemotherapy. Incidents identified in this stage were used in stage three

Stage Three – A qualitative study using the Critical Incident technique to explore the contributory causes of preparation and administration errors in chemotherapy

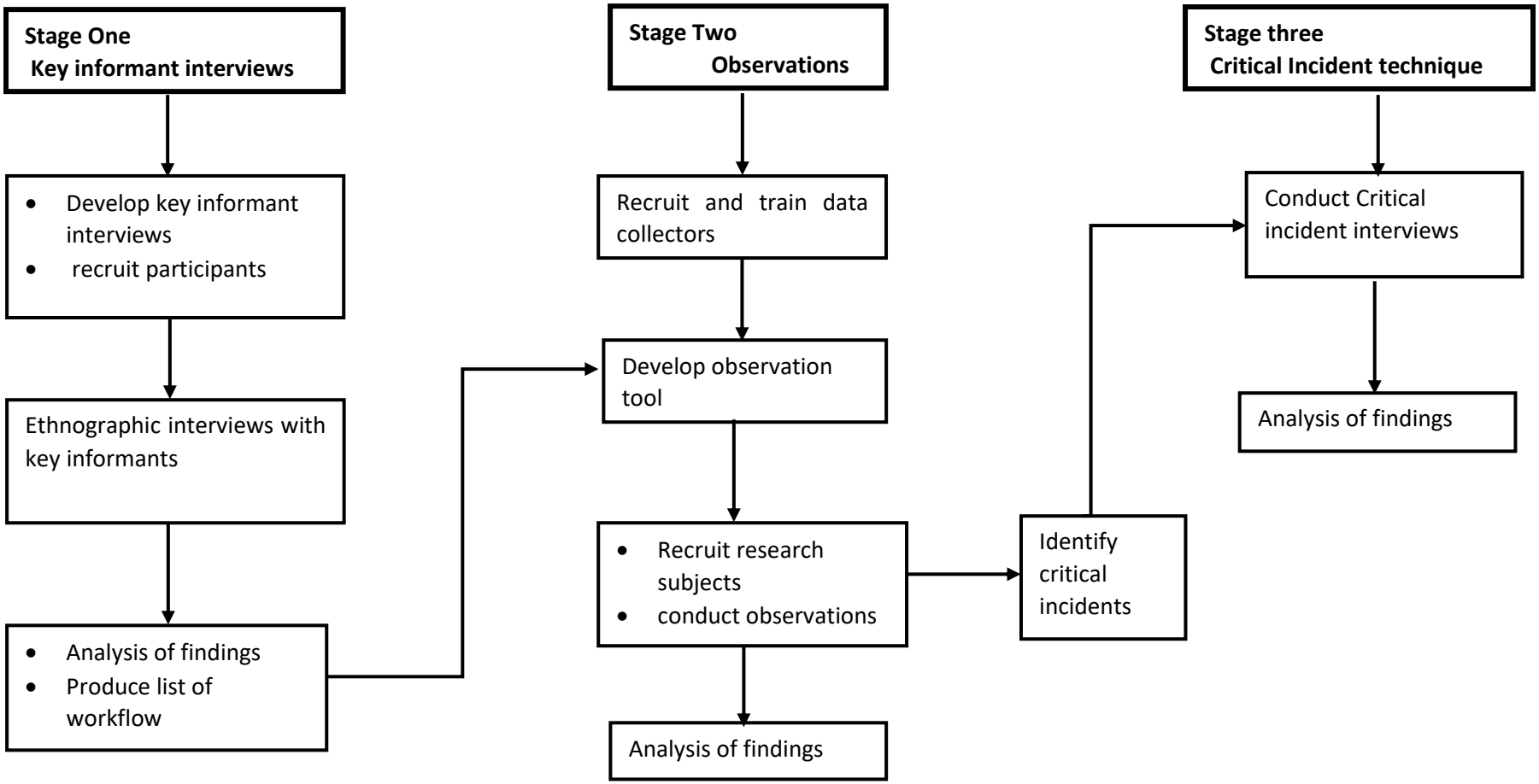


Figure 5-1 Flow diagram showing study design

5.4 Stage one: Description of the preparation and administration process

The aim of this study was to obtain a description of the chemotherapy preparation and administration process in order to inform the design of an observation tool to be used in the second stage. While researching patient safety culture (see Chapter 3), it became evident that written SOPs were not used routinely, and hence a description of work processes was not readily available. This stage of the study used key informant interviews to establish how nurses prepare and administer chemotherapy.

5.4.1 Sampling and sampling technique

Purposive sampling method was used because the views of experienced nurses were important to provide valuable input into describing work practices in the chemotherapy ward.

In the study hospital, the supervisory nursing team consisted of two matrons and four senior nurses, who were identified as potential participants. Both matrons were educated to at least university level and three of the four senior nurses were educated to diploma level. After discussions with the research supervisors, it was decided to approach both matrons and invite them to participate in the project and in the event of either or both declining to participate the university-educated senior nurses would be approached. Nurses were given a PIL (Appendix 5-1) and consent form (Appendix 5-2) to read and sign prior to the interviews.

5.4.2 Development of the Interview Schedule

The interview schedule was developed using the principles outlined by Spradley (1979), using grand tour and mini tour questions.

Interviews were designed to last between 30-45 minutes in order to avoid interview fatigue and minimize the impact on service delivery. The schedule covered six topics; introduction to assure consent and confidentiality, questions around the workflow in the chemotherapy administration area, the process of chemotherapy preparation and administration, the skill mix in the day ward, types and causes of medication errors, preventative action taken against medication errors and interview closure (Appendix 5.3). Prompts were used throughout the interview to encourage the interviewee to increase the richness and depth

of the information provided and to support dialogue between participant and researcher. Prior to administration of the interview schedule, the content and wording were repeatedly reviewed by the supervisory team and changes were made to remove ambiguity and irrelevant questions.

5.4.3 Stages of Preparation and Administration as identified by key informant interviews

The findings from the key informant interviews were categorised and summarized to provide steps for the workflow in the chemotherapy day ward. The steps identified, comprised; receipt of chemotherapy in the day ward, preparatory work, preparation of chemotherapy and supportive drugs and administration of chemotherapy supportive drugs (Table 5-1).

The findings from this stage were used to inform the development of an observation checklist similar to ones used in previous medication error research (Taxis et al., 2003a;Taxis et al., 2003b). Methods used to develop the check list are detailed in the next section.

5.5 Stage Two

A review of the methods adopted in the investigation of medication errors has shown that observation methods were able to identify patient harm, active errors, latent causes and contributory factors to errors (Michel, 2003). Observation is defined as:

> "*a research method in which the investigator systematically watches, listens to and records the phenomenon of interest" (Bowling 2005 p 605)*

Observation allows the investigator to gather data without the direct involvement of participants and hence doesn't suffer from response bias, recall bias or the need for complete records.

Observation methods have since become the standard for assessment of administration errors (Tissot et al., 2003;Wirtz et al., 2003;Taxis et al., 2003a). They are superior to incident reports and questionnaires which only identify less than one tenth of those identified by observation methods (Barker et al., 2002a). The reliability of the results of observational methods can be confirmed by using a two-step process where an expert panel reviews the errors to confirm their validity (Dean et al., 2001).

Table 5-1 Stages of preparation and administration of chemotherapy and supportive medicines

Process	Description
Receipt of chemotherapy on the ward	Patients wait in their beds before the arrival of the nurse. Chemotherapy medicines are sent by a porter from pharmacy, who places the medicines bag next to the patient on their bed.
Preparatory work	Nurse arrives on ward and starts to gather equipment necessary for preparation of intravenous medicines An intravenous access device is inserted in patients waiting on beds.
Preparation of chemotherapy and supportive medicines	Nurse reads patient prescription and verifies that the correct medicines have been sent from the pharmacy. The pre-medication which consists of anti-emetics and other supportive drugs is prepared for all patients on the ward Each patient's intravenous chemotherapy is prepared, labelled and placed on the patient's bed.
Administration of chemotherapy and supportive medicines	Supportive medicines and pre-medication is administered to patients. Chemotherapy is administered to the patients according to guidelines in the administration sheets, which details the infusion rate and dictates which medicine is infused first The last step is flushing the line with sodium chloride 0.9%.
Disposal	Vials of cytotoxics are disposed in allocated plastic bags. Sharps are disposed in allocated sharps disposal units.

There were early concerns about the "Hawthorne effect" where HCWs may be affected by overt observation to change their behaviour (Patton, 1990). However, Barber and Dean (2001) confirmed that these concerns were unfounded because, during a study of administration errors in a UK hospital, there were no differences between omission errors in the observed wards versus the non-observed wards. In their study, Barber and Dean (2001) offered partial explanations to the nurses regarding the true purpose of the study, a

method that has been criticised (Armitage, 2005). Armitage (2005) argued that in order for medication error research to achieve its optimum targets and appropriate research ethics, participants should be consented and fully informed of the true purpose of the study (Armitage, 2005). Observation methods, however, have other limitations, namely cost and time and the need for careful training of the observer.

Two methods for observation have been used in healthcare; participant and non-participant observation. The latter will be used in this current study because participant observation is more suited to qualitative research. Non-participant observation is more commonly undertaken during quantitative research (Smith, 2002), where

> *"the observer is independent of the setting" (Smith 2002 p 82)*

The process of non-participant observation requires that the data collector be present in the research setting to record daily events according to a pre-determined agenda (Smith, 2002). Non-participant observations have been used in previous medication research to identify the incidence of intravenous preparation errors in hospital clinical areas (Crowley, 2006) and in identification of medication administration errors in hospital wards (Taxis et al., 2003b).

For the purposes of data collection, a research team consisting of two pre-registration pharmacists were recruited and trained in observational methods. The following section explains the recruitment and training procedures followed regarding the research team.

5.5.1 Research Team

After obtaining approval from the chief pharmacist at the study hospital, two pre-registration pharmacists, towards the end of their training, were approached and briefed on the background to the study.

5.5.1.1 Training of Research Team

The data collectors were trained in patient safety research, chemotherapy day ward orientation and preparation and administration of chemotherapy and direct observation as outlined below.

Patient safety research

The research team were instructed on the principles of medication error research using a WHO training package which provided principles of patient safety illustrated by a video that detailed the RCA of an error involving the injection of intrathecal vincristine (WHO, 2008a). The video was narrated by Sir Liam Donaldson and contained a description of patient safety research and findings to date. The intention of this step was to educate the data collectors on patient safety issues, in preparation for data collection.

Day ward orientation

Both data collectors shadowed a ward-based clinical pharmacist for a week to observe the organization of the day ward, workflow, patient/HCW interaction and the processes followed for preparing and administering chemotherapy in the day ward. This was to familiarize the data collectors with work flow in the day ward and the procedures followed during preparation and administration of chemotherapy.

Preparation and administration of intravenous chemotherapy

In order to ensure that the data collectors are aware of the appropriate steps to be followed when preparing intravenous preparation, they were shown a video on the preparation and administration of chemotherapy developed by ASHP. The principal researcher was present throughout the video session to respond to queries and comments.

Practical training on the preparation of intravenous medicines followed, to ensure the data collectors had a sound knowledge of appropriate procedures. The hands-on training involved aseptic manipulation of intravenous doses which comprised reconstitution of vials and ampoules and the addition of medicines to intravenous fluids. This was observed by the principal researcher to ensure accuracy of the procedures followed.

For the purposes of improving knowledge regarding chemotherapy preparation and administration, data collectors shadowed a senior nurse on the ward to observe the procedures followed. In addition, data collectors studied the NRLS procedure for administration of chemotherapy (Pan London, 2011) because it was possible that the senior nurse may have drawn on the practices commonly followed at the study hospital rather than being guided by best practice.

Direct observation

The last step necessitated training the data collectors in methods of direct observation, a method adopted by researchers in medication error studies (Barker et al., 2002b). They

were given a draft data collection sheet to record their observations of nurses on the day ward with the principal researcher conducting separate observations on the same nurse. Observation records were compared at the end of each day to identify any discrepancies that occurred. Further training was then provided to rectify any identified issues. This process was continued for three days until it was affirmed that the data collectors were able to identify all actions during the nurse observations in a reliable and valid manner.

Both data collectors were present at all the training sessions in order to ensure that consistency was maintained in their observations.

5.5.2 Development of the observation tool

The initial draft observation tool (Appendix 5-4) was informed by key informant interviews, previous medication error research (Crowley, 2006;Taxis et al., 2003a;Allwood et al., 2002) and the injectable medication audit (Appendix 5-5) developed by the NRLS (2007). In addition to the processes stated by the NRLS (2007), it was important to record errors of aseptic procedure because patients on chemotherapy are more likely to have poor immunity, making them more prone to developing infections. An additional component to be observed was staff protection because chemotherapy is potentially carcinogenic, mutagenic and teratogenic and hence operator protection was an important aspect. The draft observation tool was divided into three sections, comprising the main processes involved in cytotoxic chemotherapy administration; preparation, administration of dose and safe disposal.

Each section was further subdivided into steps according to information obtained from the literature (Joshi, 2007;ASHP, 2002;Allwood et al., 2002) Appendix 5-5. The observation tool was revised by the supervisory team for inconsistencies and errors which were corrected prior to the piloting stage.

5.5.2.1 Pilot Study

After completion of training, the researchers were asked to pilot the data collection tool by observing nurses prepare and administer chemotherapy on the outpatient chemotherapy day ward. The objectives of the pilot were as follows:

- Testing, refining and validating the observation tool.
- Quality assurance for assessing the observation skills of the research team.

Piloting of quantitative research tools has been undertaken in medication error research using a sample of 50 (Dean et al., 1999). In the study hospital, each nurse would prepare chemotherapy for 3-4 patients each requiring 1-7 intravenous medicines. Hence a chemotherapy day ward nurse may prepare an average of 60 items per week. It was decided that the pilot could be conducted on 50-60 doses or until there were no more alterations to be made on the tool. Alterations to the final data collection tool (Appendix 5-6) were carried out after daily meetings with the principal researcher and comprised the following changes:

1- The final draft observation tool was to include observations for three medicines rather than one medicine per sheet to reduce observer fatigue.
2- Changes were made on the preparation of dose stage where a step for addition to intravenous fluid was added.
3- Changes were made to the disposal section to record disposal into the chemotherapy bin and disposal of sharps separately.

5.5.3 Recruitment of research subjects

Convenience sampling is a technique used to recruit research participants who are accessible and willing. It is the least costly sampling strategy, but is less rigorous than others and may introduce bias into research (Marshall, 1996). However, this was the most appropriate sampling strategy in the current study because it was identified while carrying out the research in Chapter 3 that nurses at the study hospital showed reluctance when approached to participate in focus group discussions. Furthermore, selection bias would be reduced because all the nurses working at the chemotherapy day ward were involved in the same activities (preparing and administering cytotoxic chemotherapy) in the same environment. There was a total of 19 nurses working on the chemotherapy day ward, of whom 14 were female nurses who run 7 female rooms, and the others are males responsible for running the 5 male rooms.

After obtaining permission from the hospital administration and the matron, all nurses were invited to attend two separate meetings, one for each gender. An oral presentation was delivered that included a synopsis of the project as follows:

1- General aims and objectives of the project.
2- The intended observation procedure that required a data collector to shadow a nurse throughout the day.

3- Nurses' activities and errors would be recorded maintaining confidentiality and anonymity.
4- Nurses involved in errors may be invited to take part in an interview.

Each nurse was given a project information leaflet (PIL) that contained written information on the above and issues of confidentiality as well as the principal researcher's telephone number to contact if they had any enquiries (Appendix 5-7). They were all asked to read the leaflet and if they agreed to participate to contact the principal researcher. After one week, no phone calls were received and hence a repeat visit was made to the ward to enquire if the contents of the PIL were understood and to directly ask the nurses if they were willing to participate. On the female ward, eight nurses expressed willingness to participate and four nurses from the male ward.

Each nurse was then given a consent form to read and sign (Appendix 5-7), prior to data collection. Consent was obtained from participants verbally or as outlined in the ethics section in chapter 2 and were informed that data collection would start the following week.

5.5.4 Data Collection

Observations were carried out in periods of 6 days (one working week) using the observation tool (Appendix 5-7). Dean and colleagues (2001) used a similar time period and showed that it increases the validity of the study and allowed the observers to record actual behaviour.

On the day of observation, the data collectors were introduced to the nurse who was also shown the data collection tool. Data collectors had a data collection tool on a clipboard which allowed them to follow the nurse around the ward. Observations were made on doses prepared rather than patients because during the pilot it was revealed that, in some instances, more than one nurse may be involved in preparing the medicines for one patient. Hence, it was decided to focus on the doses prepared by one nurse because it would have been impractical to observe more than one nurse at a time,

On days of data collection, data collectors were instructed to be present and ready on the ward at 8:30 am regardless of the times that the nurses arrived. On arrival of the nurse, they would start data collection by following the nurse and recording the procedures involved. Data collectors were instructed not to intervene in unimportant activities; for example, inappropriate disposal of cytotoxics vials or inaccurate. However, in situations where the

patient would be likely to be adversely affected, they were instructed to discreetly intervene. These instances were:

1- The wrong medicine was chosen.
2- The medicine was not diluted using the correct dilution volume and there were visible powder particles in the vial.
3- The wrong calculation for dose volumes was performed.
4- The volume withdrawn was inaccurate.
5- An essential medicine was missed.
6- The infusion rate was inaccurately adjusted with paclitaxel and cisplatin.
7- The nurse neglected flushing the intravenous line with sodium chloride 0.9% after injecting a vesicant medicine.
8- The nurse was seen to discard sharps in areas where patients and hospital staff would be at risk of injury.

A medication administration error was defined as follows:

> *"A deviation in the preparation or administration of a medicine from a doctor's prescription, the hospital IV policy or the manufacturer's instructions" (Taxis and Barber 2003b p 344)*

Explicit categorisation of medication administration errors was adapted from NRLS (2007) standard operating procedure for the prescribing, preparation and administration of injectable medicines (Appendix 5-5).

After completion of two weeks (10 working days) of observations, the data collectors moved to a separate ward to complete the observations on a different nurse.

5.5.5 Analysis of observation results

Quantitative analysis was undertaken for findings from the observation study. In addition, the risk of error and microbial contamination of each observed drug was assessed as explained in the following sections.

5.5.5.1 Risk assessment of injectable medicines

As all the observed intravenous medicines, were prepared on open benches, it was necessary to assess their risk for error and bacterial contamination. Beaney (2010) developed an intravenous product risk assessment tool, for use within the UK NHS, that

used weighting for certain items to aid risk scoring of medicines (see Table 5-2). The purpose of the risk assessment tool was to identify intravenous medicines that have a high risk of error or bacterial contamination during ward-based manipulations (Beaney, 2010) and recommended that high risk intravenous medicines (those with a score of more than 6) should be prepared in a centralized setting such as a pharmacy aseptic unit, rather than on open benches on wards.

An expert panel was formed comprising two clinical oncology pharmacists and a senior pharmacist responsible for stock rotation and procurement. Each pharmacist was given the frequencies of error associated with observed drugs during the preparation and administration of chemotherapy one week before the meeting of the expert.

A meeting was held with members of the expert panel where points of concern were clarified. The objectives of the meeting were as follows:

- Present the aims and objectives of the project.
- Explain the findings of the observation study and the purpose of the activity.
- Identify the medicines with highest risk to prioritise when designing an intervention to reduce the error rate at the hospital in the future.
- Present the method for risk assessment of the medicines involved in the observation period as described by Beaney (2010)

During the meeting, each of the pharmacists was given copies of the manufacturer's recommendation for the reconstitution of each medicine.

The expert panel discussed the above tool and it was decided to modify it as follows:

1- Category F was replaced by extravasation risk. Chemotherapeutic agents have additional administration concerns; mainly their ability to cause necrosis when extravasation occurs during intravenous administration. A previous undergraduate research project showed that the rate of extravasation at the study hospital was 15% (Mohammed, 2006), more than double the range identified in the literature (Ener et al., 2004). Risk of harm from extravasation depended on the effect of chemotherapeutic medicine on human tissue. Therefore, the medicines were grouped and classified into: neutral, inflammatory, irritant, exfoliant or vesicant according to published literature (Ener et al., 2004;Allwood et al., 2002). It was decided to give a different weighting to each class depending on the severity of

potential damage, as follows: Neutral=0, inflammatory=1, irritant=2, exfoliant=3 and vesicant= 4.

2- Category K was removed because the observation study didn't involve recording the patient's co-morbidities.

3- An extra category involving the requirement for adjusting the rate of administration was added to the tool because this was necessary for some cytotoxic medicines such as paclitaxel where a fast rate can cause cardiac side effects (Summerhayes et al., 2003).

Table 5-2 Risk Assessment of intravenous medicines *(Beaney, 2010 p1572)*

Code	Risk		Weighting
A	Number of manipulations		1 each
B	Calculations		2 each
C	Part usage vials and ampoules		1
D	Background environment	Theatre	0.5
		Intensive Care setting	1
		Ward	1.5
E	Nature of material e.g. teratogenic, mutagenic		3
F	Nature of material e.g. microbiological contamination		3
G	Route of administration	IT	5
		Epidural	3
		IV	1
		IM/SC	0.8
H	Duration of administration	7-day device	3
		24-hour infusion	2
		Other infusion	1.5
		Slow IV	1
		IV/IM/SC bolus	0.5
I	Unfamiliar Process (defined as less than 6 amps/vials used in 12 months		2
J	Special needs patient e.g. neonate, renal failure, immunocompromised, ITU patient, fluid restricted		1.5
K	Dangerous practice e.g. unlabelled syringes pre-prepared		1.5

The new risk assessment tool was further revised to ensure consistency and that there are no inaccuracies (see Table 5-3).

Table 5-3 Modified risk assessment tool for parenteral products prepared in clinical areas

Code	Risk		Weighting
A	Number of manipulations		1 each
B	Calculations		2 each
C	Part usage vials and ampoules		1
D	Background environment	Theatre	0.5
		Intensive Care setting	1
		Ward	1.5
E	Nature of material e.g. teratogenic, mutagenic		3
F	Risk of extravasation	Vesicant	4
		Irritant	3
		Exfoliant	2
		Inflammatory	1
G	Route of administration	IT	5
		Epidural	3
		IV	1
		IM/SC	0.8
H	Duration of administration	7-day device	3
		24-hour infusion	2
		Other infusion	1.5
		Slow IV	1
		IV/IM/SC bolus	0.5
I	Unfamiliar Process (defined as less than 6 amps/vials used in 12 months		2
J	Special needs patient e.g. neonate, renal failure immunocompromised, , ITU patient, fluid restricted		1.5
K	Dangerous practice e.g. unlabelled syringes pre-prepared		1.5

5.5.5.2 Descriptive Statistics

Quantitative analysis was used to present the results collected during the observations. Observations were coded and entered into statistical software SPSS v 22.0 for storage and analysis. Data cleaning was undertaken to detect and correct data entry errors, manage missing data and rectify any coding errors.

Descriptive statistics were used to analyse the results and percentage frequencies of categorical values. Percentage frequencies of drugs observed were calculated and displayed together with the drug risk scoring according to section 5.5.5.1. Percentage frequencies, percentage median and the interquartile range for opportunities for errors according to drug, nurse and stage of the administration process were calculated and displayed. In addition, Pearson Chi square test was used to find to identify if the gender, level of experience of the nurse was associated with errors. A chi square result of <0.05 was considered a significant association.

5.5.6 Results:

5.5.6.1 Characteristics of drugs observed

The preparation and administration of 378 cytotoxic medicines and supportive drugs were observed over an eight-week period, representing 12772 opportunities for error. An overwhelming number of errors occurred during each observation. A total of 8684 (68%) errors were recorded for eight different groups of medicines observed during the study period, representing 19 chemotherapy agents and 10 medicines used in supportive care (see Table 5-4). The most commonly observed medicines were the antiemetics (115; 30.4%) among supportive medicines and antimetabolites (55; 14.6%) among cytotoxics.

The medicines involved in the observation period were assessed using the risk scoring system outlined in the analysis of results section 5.5.5.1. The injectable drug risk assessment scoring identified that all of the observed cytotoxics and all of the medicines used in supportive care scored above 6 (Table 5-4). Beaney (2010) proposed that intravenous medicines that have a score of more than 6 are high risk medicines that should be prepared in a centralised pharmacy under aseptic conditions. Hence, all observed medicines were categorised as high risk.

Table 5-4 Characteristics of drugs observed

Drug group	Frequency of drug group observations (%)	Individual Drug	Frequency of individual drug observations (%)	Risk Score
Cytotoxics				
Anti-metabolites	55 (14.6)	5-Fluorouracil	45 (11.9)	15.75
		Gemcitabine	7 (1.9)	31.5
		Methotrexate	2 (0.5)	15.75
		Cytosine-Arabinoside	1 (0.3)	15.75
Platinums	43(11.4)	Cisplatin	33 (8.7)	15.75
		Carboplatin	10 (2.6)	15.75
Alkylating agents	37(9.8)	Cyclophosphamide	22(5.8)	31.5
		Ifosfamide	7(1.9)	31.5
		Dacarbazine	8(2.1)	31.5
Anthracyclines	32(8.5)	Doxorubicin	23(6.1)	15.75
		Epirubicin	7 (1.9)	15.75
		Dactinomycin	1 (0.3)	31.5
Taxanes	25(6.6)	Docetaxel	18 (4.8)	31.5
		Paclitaxel	7 (1.9)	31.5
Vinca alkaloids	18(4.8)	Vincristine	13(3.4)	15.75
		Vinblastine	4(1.1)	15.75
		Vinorelbine	1(0.3)	15.75
Other cytotoxics	15 (4.0)	Bleomycin	8(2.1)	31.75
		Etoposide	5(1.3)	15.75
		L-Asparaginase	1(0.3)	30
Supportive Medicines				
Anti-emetics	115 (30.4)	Dexamethasone	61(16.1)	9.75
		Ondansetron	54(14.3)	9.75
Electrolytes	20(5.3)	Magnesium Sulphate	10(2.6)	14.25
		Potassium Chloride	10(2.6)	14.25
Other supportive medicines	18(4.8)	Mesna	8(2.1)	22.5
		Chlorphenamine	2(0.5)	9.75
		Folinic Acid	5(1.3)	9.75
		Ranitidine	2(0.5)	9.75
		Mannitol	1(0.3)	11.25
Total			**378**	

5.5.6.2 Errors associated with cytotoxic chemotherapy and supportive medicines

None of the medicines prepared during the study period were observed to be correctly prepared or administered. Observers recorded 8684 (68%) errors, (percentage median 67.6%, IQR= 11.6%) of total opportunities for errors (Table 5-5). Each observed dose represented a maximum of 38 and a minimum of 31 opportunities for error and each was involved in a minimum of 15 errors up to a maximum of 32 errors. Interestingly, the number of errors was inversely associated with the number of opportunities for error per dose (p=0.003, chi square test). The highest frequency of errors occurred with vinca alkaloids (percentage median error rate 75%, IQR=11.8) and the lowest frequency of errors occurred with alkylating agents (percentage median error rate 63.2%, IQR=5.3%).

5.5.6.3 Characteristics of nurses observed and associated errors

A total of 8 nurses gave consent to participate in the study, representing an equal number from each gender, all were staff nurses with varied lengths of experience (see Table 5-6). Nurses were observed to be involved in errors in the majority of doses. The highest frequency of errors was recorded (percentage median error rate 79.1% IQR=6.5%) with a nurse who had 1-5 years of experience and the lowest frequency of errors (median error rate 58.1%, IQR= 8.4%) were observed with a nurse who had more than 5 years' experience. Although there was no significant association between staff gender and the total number of errors made per dose (p-=0.74, Chi- square test), a significant statistical association was seen between length of service and the number of errors (p<0.000, Chi-square test) where staff with less than 5-years' experience were more likely to be involved in errors than those who had more than 5- year experience.

Table 5-5 Analysis of dose error per drug

Drug Group	Total opportunities for error	Frequency of error (%)	%Median(IQR)
Antimetabolites	1860 (14.6)	1229(66.1)	64.7 (71.7-60.6)
Platinums	1450 (11.4)	972 (67.0)	66.7 (70.6-60.6)
Alkylating Agents	1376 (10.8)	894 (65)	63.2 (65.8-60.5)
Anthracyclines	1084 (8.5)	748 (69.0)	67.6 (75.8-63.6)
Taxanes	935 (7.3)	608 (65.0)	64.9 (70.3-57.9)
Vinca	612 (4.8)	456 (74.5)	75.0 (82.4-70.6)
Other Cytotoxics	532 (4.2)	368(69.2)	64.9 (77.9-62.0)
Antiemetics	3699 (30)	2548(68.9)	68.8 (71.9-62.5)
Electrolytes	648 (5.1)	458(70.7)	71.2 (78.1-63.4)
Other Supportive Medicines	576 (4.5)	403 (70.0)	68.2 (74.8-65.6)
Total	**12772**	**8684(68)**	**67.6 (84.6-73)**

Table 5-6 Analysis of error per nurse observation

Observation (8weeks)	Gender	Observed Nurse length of experience	No of observed doses	Frequency of observed opportunities for error	Frequency of errors (%)	%Median (IQR)
1	F	1-5 years	64	2153 (16.8)	1397 (64.9)	64.1 (69.8-61.5)
7	M	More than 5 years	64	2112 (16.5)	1526 (72.2)	71.2 (75.8-68.8)
5	M	More than 5 years	63	2105 (16.5)	1239 (58.8)	58.1 (62.5-54.1)
2	F	Less than 1 year	52	1783 (14.0)	1395 (78.2)	79.2 (84.8-73.4)
3	F	Less than 1 year	41	1411 (11.0)	878 (62.2)	62.2 (64.7-59.4)
6	M	1-5 years	35	1191 (9.3)	778 (65.3)	65.6 (68.8-62.0)
8	M	1-5 years	30	1028 (8.0)	814 (79.1)	79.2 (82.4-75.9)
4	F	Less than 1 year	29	989 (7.7)	657 (66.4)	66.7 (70.6-63.2)
Total			**378**	**12772**	**8684 (68%)**	

5.5.6.4 Types of errors during preparation of cytotoxic medicines

The data obtained from the observation of dose preparation was analysed according to subs-stages. Preparation of cytotoxics and the supportive medicines involved six stages each composed of several sub-stages (see Figure 5-2). An overwhelming number of errors were recorded during observations of each preparation sub stage.

While preparing cytotoxic and supportive medicines, on the ward, none of the nurses wore goggles or protective footwear required for personal protection against occupational exposure to cytotoxics. On a minority of occasions nurses did not wear a protective coat (8%) or gloves (3.6%). Major deviations from aseptic procedure were also observed as, on all occasions, nurses never washed their hands or cleaned work surfaces or swabbed the drug vials with alcohol and never adhered to non-touch technique, an important requirement for preparation of intravenous doses (Beaney, 2010).

Observers recorded that more than one third (39%) of all doses were calculated incorrectly and during preparation of the vast majority of doses (97.6%), a second check on calculation was not obtained. The observer intervened in all cases to prevent errors reaching the patient. Observers recorded that even after correcting the calculation, 16.9% of dose volumes were removed inaccurately, requiring further intervention from observers to correctly adjust the volume. In the majority of occasions, the drug was added to the intravenous fluid without obtaining a second check (90%).

Observers identified that labelling requirements were never followed as none of the prepared medicines contained information relating to the route of administration, the time prepared, the final concentration or the initial of the nurse involved in the manipulation. Essential information was absent in the majority of cases, for example; the patient name was not included in 99%, of doses; the drug name was not recorded in 85% of cases; and the dose was rarely documented (99%).

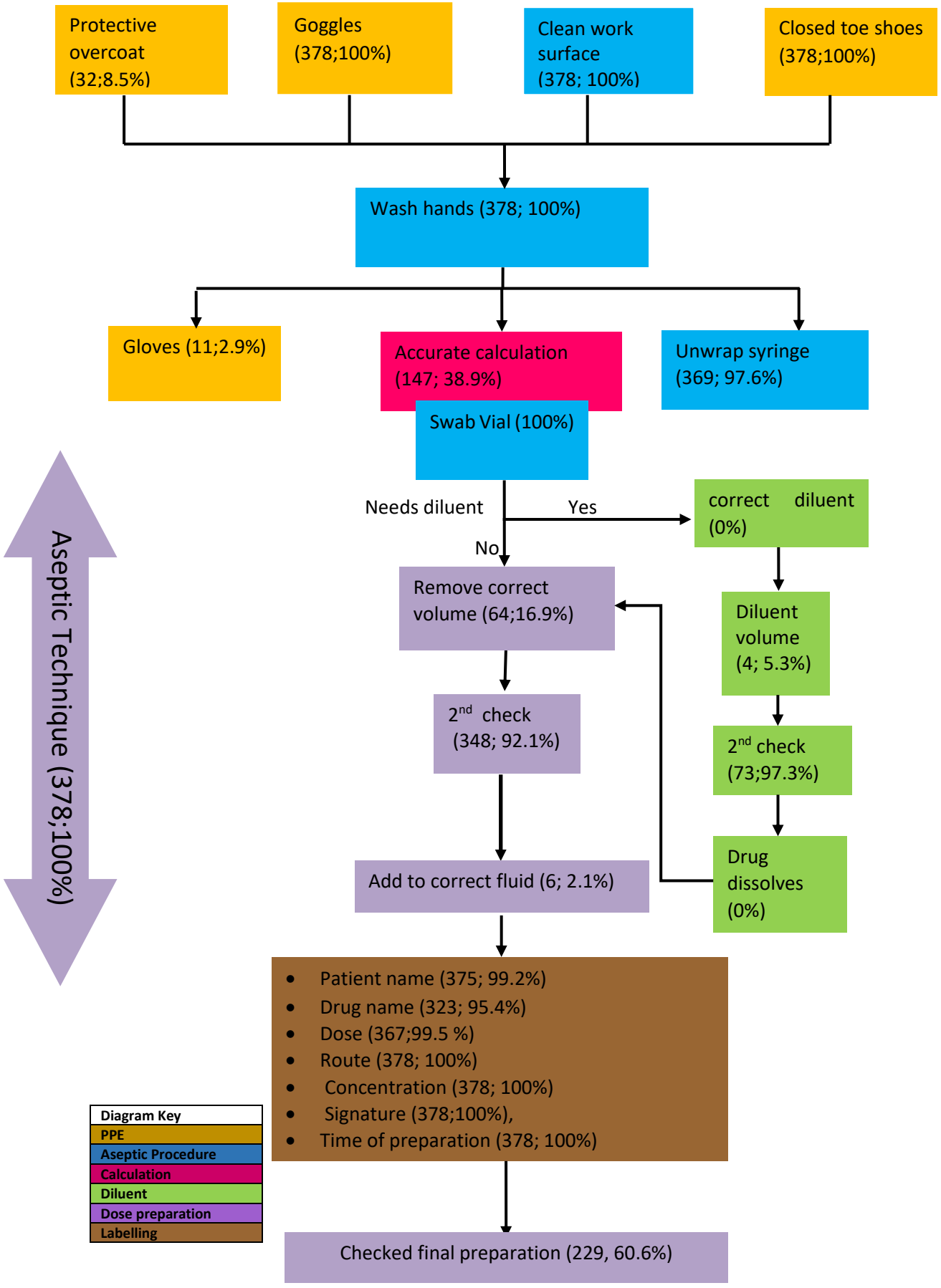


Figure 5-2 Errors at each sub-stage of drug preparation

5.5.6.5 Types of errors during administration of observed medicines

Administration of both cytotoxics and supportive medicines involved ten sub stages and their disposal involved two sub stages (see Figure 5-3). A substantial number of errors occurred during administration of medicines. In all cases nurses failed to record the details of medication administered in the patient's notes, and failed to confirm the patient's allergy status. Nurses failed to verify the patient's name in the majority of observations (90%) and did not read the prescription details on the medication chart before administering the medicine in nearly half (41%) of observations. In a little more than a quarter (26%) of occasions, the nurses started to administer medicines using an incorrect administration sequence and incorrectly adjusted the infusion rate for over half the medicines (56%). During the infusion of 56% of observations, nurses left the patient unattended and failed to monitor the infusion site and the flow of the infusion. Observers intervened to correct administration sequence and infusion rate.

5.5.6.6 Errors per stage

Further analysis was then undertaken to investigate the frequency of error during each whole stage. The observation of medication administration process (preparation, administration and disposal of waste), involved 8 stages. A considerable number of errors occurred at all stages of the medication administration process. Two thirds of the doses (59.1%) were incorrectly administered (percentage median 55.6%, IQR=26) and the incorrect calculation process was followed in more than two thirds of the doses (68.3%). Almost all nurses consistently breached aseptic technique with 99.4% of the steps either inaccurately performed or not undertaken (percentage median 100%, IQR=0), and omitted essential information during the labelling of 99.4% of doses (percentage median 100%, IQR=0). The lowest frequency of errors occurred at the disposal stage where 88 (14.3%) errors occurred.

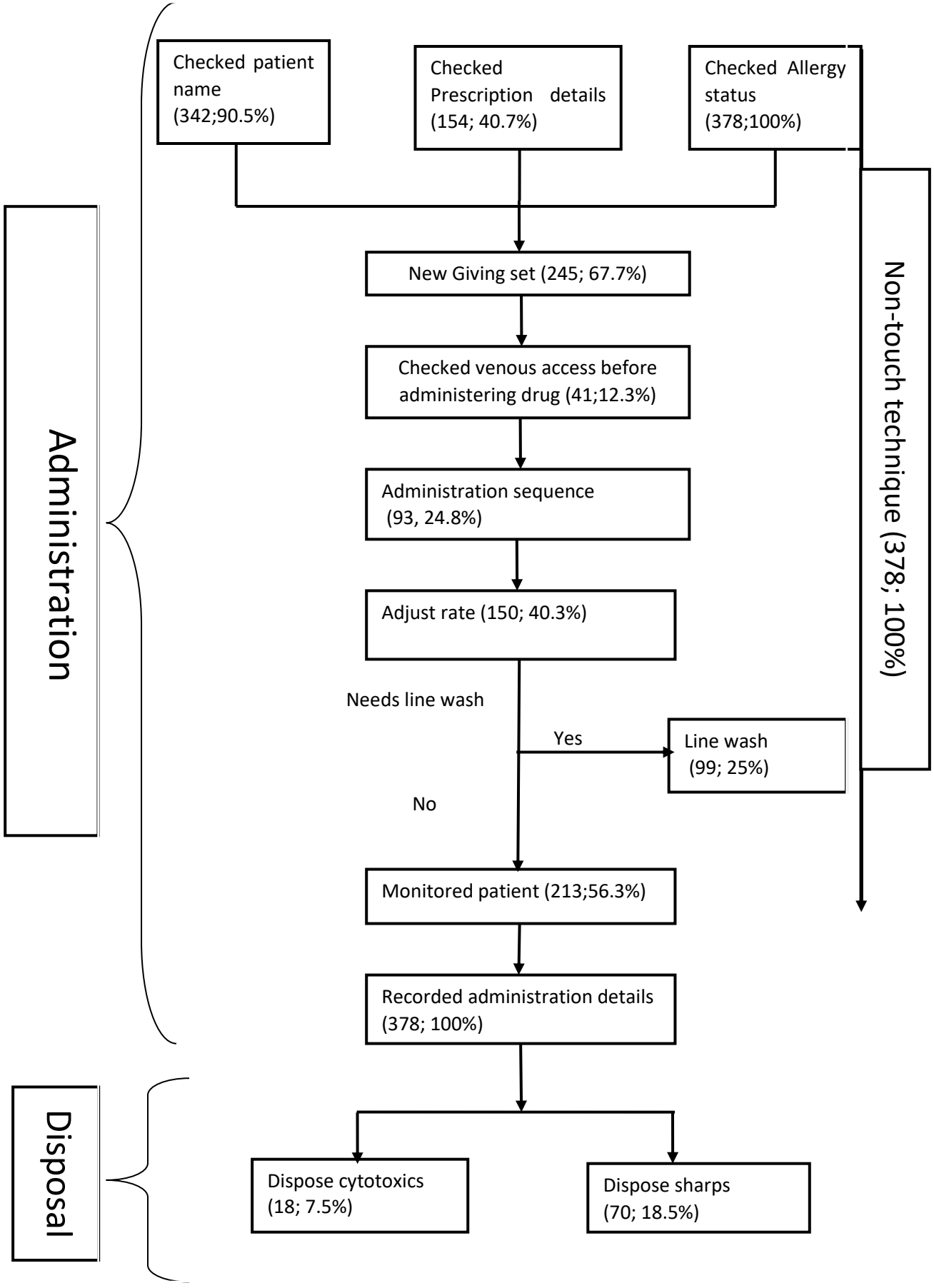


Figure 5-3 Frequencies of errors at each sub-stage of medication administration

Table 5-7 Analysis of errors per stage

Stage errors	Total opportunities for error (%)	Frequency of errors (%)	%Median(IQR)
Administration of dose	3542 (27.7)	2093(59.1)	55.6 (70.0-44.4)
Labelling of final product	2646 (20.7)	2586(97.7)	100 (100.0-100.0)
Aseptic technique	1890 (14.8)	1878(99.4)	100 (100.0-100.0)
Personal Protective Equipment	1512 (11.8)	799(52.3)	50 (50-50)
Preparation of dose	1509 (11.8)	647 (42.9)	50 (50.0-25.0)
Calculation	756 (5.9)	516(68.3)	50 (100.0-50.0)
Disposal of vials and sharps	617 (4.8)	88 (14.3)	0.0 (0.0-0.0)
Diluent	300 (2.3)	77 (25.7)	25 (25.0-25.0)
	12772	**8684**	

5.6 Stage Three

In the current study, direct observation (stage 2 of the current chapter) collected critical incidents from the eight nurses at the chemotherapy ward. The critical incident here was defined as a preparation or administration error, categorised in Appendix (5-5).

5.6.1 Interview Schedule

The CIT was used to develop an interview schedule (Appendix 5-8). Flanagan (1974) provided detailed instructions on data collection and proposed that this could be done using either observations or interviews. The interviews are required to be worded in a specific way so as to prevent inferences from research participants and to encourage actual accounts of the critical incident (see Chapter 4). Research participants were asked to focus on a specific incident with questions probing the behaviours involved. To ensure that recall would not be compromised, research participants were interviewed within 96 hours of an error taking place. The interview schedule (Appendix 5-9) was designed to last between 30-45 minutes and consisted of the following: Introduction, a description of the environment at the time of the incident, a description of the preparation and administration process, a

detailed description of the nature of the incident, Identify the effective/ ineffective actions, needs, and a closure.

5.6.2 Recruitment of research participants and selection of critical incidents

Research participants were recruited into this study after identification of a critical incident. Although they had previously consented to take part in the observation study, research participants were approached separately for the interviews. Initial findings from the study indicated that nurses were involved in multiple errors each day and hence it was discussed with research supervisors that repeated interviewing would not be constructive; hence the critical incident interview focused on one critical incident per nurse. The critical incident in this situation was the first error committed on the day of data collection. All research participants were asked to separately provide consent to this study, but refused to provide written consent. Hence verbal consent was audio-recorded before the start of each interview, following the principles outlined in Chapter 2 of the current thesis.

5.6.3 Data management and analysis

Data was recorded using digital recorder SONY (ICD-BX800), and verbatim answers were transcribed in Arabic. The transcribed interview was translated using methods outlined in the Chapter 2.

Translated data were entered into NVivo for storage and data analysis. Framework analysis based on Reason's Framework of Human Error (described in previous sections) was used for the analysis (Reason, 1990). The critical incidents were classified into categories of human error: slips, lapses, violations and mistakes. Critical behaviours were categorised using Reason's Framework as organizational processes and pre-conditions for errors.

Further interpretation of the data were undertaken using Reason's culpability tree (Reason, 1997) (see Figure 5-5) because it was necessary to take nurse accountability into consideration when discussing the results of this study. HCW accountability in relation to medication errors is a necessary component of a just culture (Wachter et al., 2009;Khatri et al., 2009).

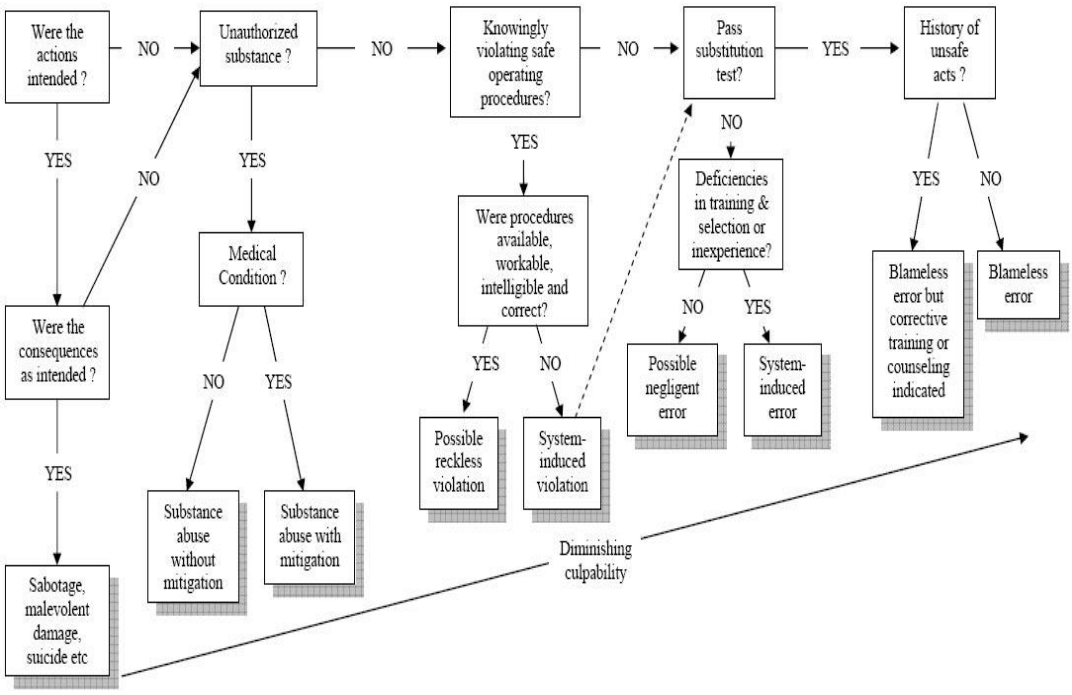


Figure 5-4 A decision tree for determining culpability of unsafe acts (Reason p 209)

5.6.4 Results

During the 8-week study period, eight nurses were observed, each for a whole week, preparing and administering cytotoxic chemotherapy to cancer patients attending the day unit at RICK. The observers identified that none of the doses were appropriately prepared because in no case did the nurse follow the required aseptic procedure during preparation.

Eight critical interviews were conducted within 48 hours of completing the data collection, to discuss one error or one critical incident. Figure 5-6 below provides detail of the errors discussed.

5.6.4.1 Categories of unsafe acts

Following analysis of interviews using Reason's Human Error framework the errors were classified into violations, slips or mistakes. The analysis revealed that there were 3 violations, 3 mistakes and one slip (Figure 5-6). This analysis was based on theme emerging from nurse critical incident interviews.

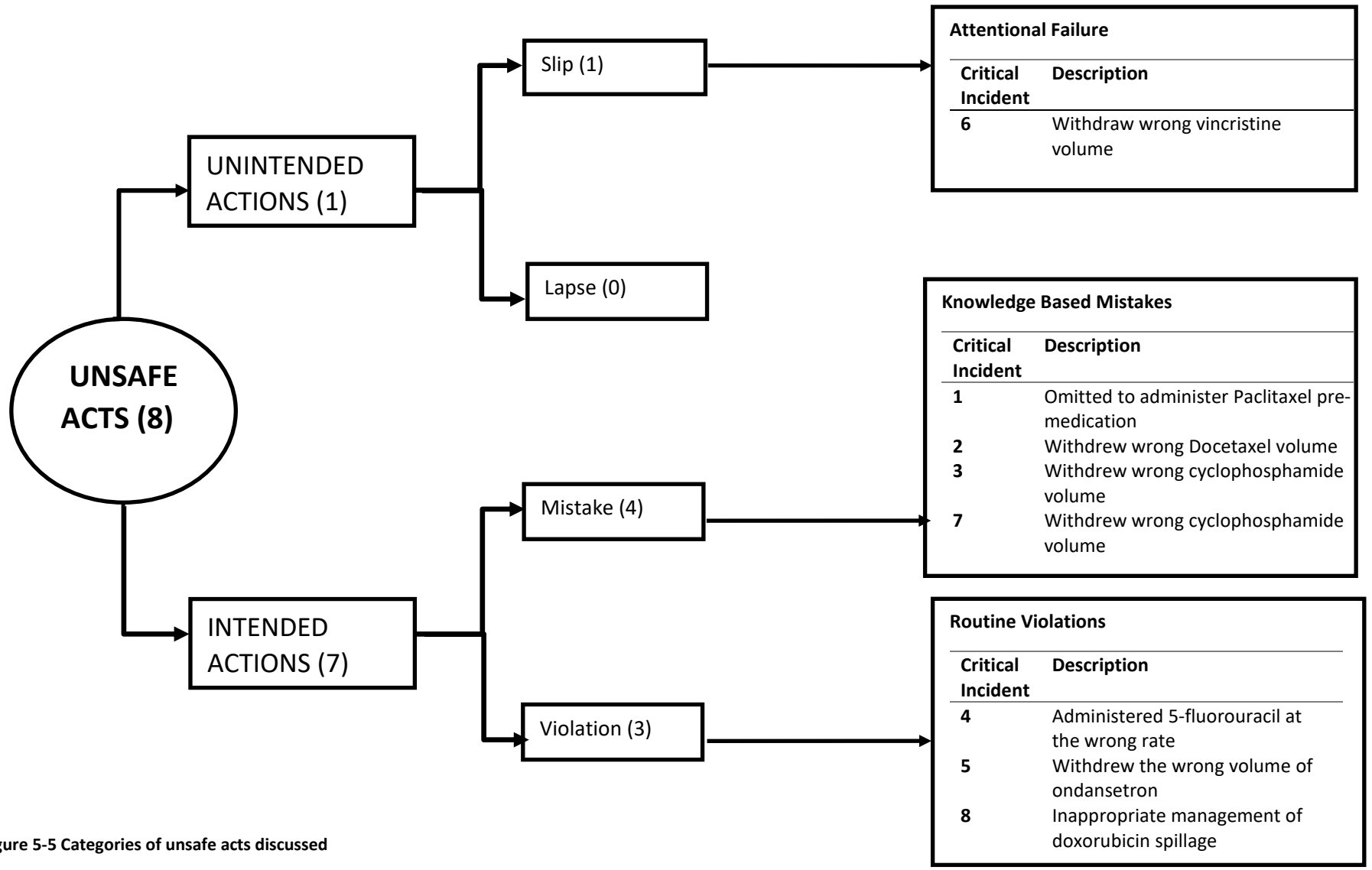


Figure 5-5 Categories of unsafe acts discussed

5.6.4.2 Contributory causes of errors

A number of latent factors and error-provoking conditions were described by nurses during the critical incident interviews. Conditions associated with medication errors were analysed using Vincent's adaptation of Reason's error framework (Table 5-7)

5.6.4.2.1 Latent factors

A number of latent factors associated with errors emerged from critical incident interviews. These were categorised into organizational and managerial factors.

Organizational Factors

During critical incident interviews, the organizational factor which was associated with most errors was lack of training.

Training

During the critical incident interviews, it was apparent that nurses showed poor knowledge in re-constituting cytotoxics and following aseptic technique. The nurses reported that they never received training targeting drug calculations, reconstitution and handling of cytotoxics. Lack of training was responsible for 5 out of the 8 critical incidents discussed in these interviews. Below is a typical quote:

> *"I mean the taxotere is a very difficult medicine to handle and the best way to deal with future errors is to avoid working with the medicine and give it to someone else to prepare. I am sure that if I was trained properly, I won't have problems preparing the medicine and it would be ok for me to do it but it would be better for someone else to do it."* **(Nurse Critical incident interview 2)**

Nurses seemed to learn the skills required for preparation and administration of cytotoxics from other nurses on the ward.

> *"during the training period, you just have to come in and observe those who are there, they do the training, we just watch and copy them later.*" **(Nurse Critical incident interview 3)**

Table 5-8 Contributory causes of active failures

Contributory causes of errors			**Active failures**						
			Unintended actions	Intended actions					
			slips	Mistakes			Routine violations		
			6	1	2	3	7	4	5	8
Latent	Organizational	Training		+	+	+	+			+
factors	Managerial	Resources			+	+	+			+
		Staffing	+			+		+		
		Policies and procedures		+	+	+	+	+	+	+
Error	Individual	New member of staff				+			+	
Provoking		Knowledge gaps		+	+	+	+			+
Conditions		Culture of short cuts							+	+
	Environment	Busy	+							
		Interruptions	+							
	Task	Complicated			+	+	+			
	Team	Supervision		+	+	+	+		+	+

Nurses' accounts revealed that training is not offered to new members of staff who are expected to improvise while undertaking tasks involving the preparation and administration of cytotoxics. A new nurse described this in the quote below:

> *"... well I came in and it was my first day and the matron told me that the other nurses on the ward were going to train me and that I have to go straight to the ward and start working. So, I came in and of course, we haven't seen or heard of chemotherapy since we graduated from school because we worked in normal general hospitals... She told me that I would be trained as I am working, so I started my work and started making up chemotherapy. It didn't seem very strange because I had prepared some drips and intravenous injections before, but the names were strange to me and I had to keep asking her (the other nurse) about how to dissolve the medicines and the volume needed and such. But on this first day, there was so much work and I wasn't concentrating because the other nurse was doing most of the work and I was mainly assisting her. When I came in yesterday... I had to wait for a whole half hour before the matron arrived, by which time the ward was full of patients and they all had their medicines bags and they were all waiting to have their doses...So really it was my second day at work and I hadn't yet learnt the names of the medicines, because really the first day, I was just assisting the other nurse on the ward. On that day, she hadn't yet arrived so I went to the matron and told them that the other nurse hadn't arrived yet and that I needed another nurse to help me. The matron instructed me to try my best to cover all the patients and if I needed any help, she would be there. She also said that she was going to come and help me read the files..."* **(Nurse Critical incident interviews 3)**

Managerial Factors

A number of managerial factors were identified during critical incident interviews. These were, deficient resources, lack of policies and procedure and staffing and workload

Resources

Nurses worked in conditions where many resources necessary for the safe preparation of cytotoxics were unavailable. These included PPE, syringes, labels, pens and calculators. One very important finding was the re-use of previously used disposable syringes. Although nurses were aware of the infection risks associated with sharing syringes between patients, they had little option in most cases but to resort to this practice. Below is a quote that illustrates this:

> *"At the same time, we don't have the right equipment but sometimes have to use one syringe to work on five different patients. I know this is wrong, I know it. But I am doing this because the syringes provided are not enough. Sometimes, I have a patient who says they cannot afford to buy any syringes. What can I do? I may go to pharmacy and they usually say they don't have any. What do you want me to do? Then they say improvise! I have to improvise with what I have. I will rinse the ones I have used for other patients and re-use them"* **(Nurse Critical incident interview 4)**

Nurses explained that they did not have access to PPE such as masks and goggles. Furthermore, each nurse is provided with a set number of gloves regardless of the requirements of the task. Below are quotes illustrating this:

> *"(looking at the data collection check list) I wouldn't consider not wearing goggles and covered shoes an error because they are not even provided. I don't even have enough gloves and not a single mask is provided for us... If I don't have a mask, when I am making the taxol, I can feel it in my head. By God, I am speaking the truth, I can smell it and feel the medicine. Taxol, taxotere and etoposide have a very powerful smell and it penetrates into my head. When I make up so many taxols, it would give me a headache."* **(Nurse Critical incident interview 4)**

> *"I get given 5 pairs of gloves to work on three patients. Each patient! can you imagine the number of drips they have, if it's a cisplatin patient, he would have cisplatin, fluids, potassium and magnesium, dexa and ondal and mannitol. You can imagine that I would have to prepare all of these infusions using only five pairs of*

gloves for my three patients and I can easily take infection from one and pass it onto the other. The problem is that this is a simple matter and its solution is simple, they(management) should just provide the equipment" **(Nurse Critical incident interview 4)**

Policies and procedures

Moreover, the nurses had no awareness of policies and procedures necessary for guidance in daily tasks and relied on instructions from others. Below is a typical quote:

"No, I wasn't aware of that before and I used to use the same drip line for all the medicines, for 4 years, until Dr A (one of the ward pharmacists) told us that we need to change the drip line. I said to my colleagues that I have been working this way for the last 4 years and it must be something new, something that they have just come up with now. Anyway, I started doing so, changing the drip line between medicines" **(Nurse Critical interview 2)**

Nurses were unaware of the appropriate procedure to remove air from vials without causing spills. As a result, while re-constituting cytotoxics, spills would occur and contaminate the environment, exposing themselves, patients, patient relatives and other HCWs to harm. The quote below illustrates this:

"but some medicines such as cisplatin have a lot of air in the vials and when you insert the needle of a syringe, the medicine spills out contaminating the gloves with chemotherapy and then you are forced to remove those gloves or sometimes you may have to wear two pairs of gloves." **(Nurse Critical incident interview 5)**

Staffing and workload

Three nurses explained that they were sometimes expected to work on their own covering a ward or a number of wards which would usually require more than one nurse. Nurses felt overworked and were not able to concentrate on their given tasks as illustrated in the quote below:

"sometimes I work with 10 patients and they want me to cover another nurse on another ward and I keep going between two rooms to do my job and they want me to work with quality in my mind. I won't be able to do it. They want me to change one patient's intravenous drip and change the drip set for another patient and straight after that a patient shouts out that their medicine has finished. If I have two

patients, then I can do my job properly. Now with three patients I can still work well but they give me 6 patients in a room and all the patients' drips stop at the same time. That causes problems. I won't be able to concentrate with these patients. I put in the cannula and then I remove another patient's cannula and then I change the medicine on the other side of the room and then I will be running about" **(Nurse Critical incident interview 4)**

On one occasion, a nurse who was covering the ward on her own was interrupted while preparing a vincristine dose and, instead of drawing up 0.4ml, she drew up 2ml which would have resulted in an overdose for the patient. The result was a slip, as illustrated below:

"Maybe I was stressed out because I was on my own… usually there are two of us working but yesterday… I had to prepare everything on my own, one of the other nurses came and gave me gloves but they were barely enough for the day. I couldn't find a mask and even the gloves were not enough and I had to go search in the other wards to find gloves and equipment. I had to prepare everything on my own; I had to put in the cannulas and prepare the medicines and administer them to the patients and all. I had no problem with all the other medicines except for the vincristine." (**Nurse Critical incident interview 6)**

5.6.4.3 Error-provoking conditions

In the presence of the previously discussed latent factors, a number of error provoking conditions were identified from nurses' accounts. These were related to the individual nurse, the task of preparing and administration of chemotherapy, team factors and environmental factors.

Individual Factors

As a result of absent policies and procedures and where training was deficient, there was evidence from five nurse interviews that they had knowledge gaps. Mistakes were mainly caused by nurses who were unaware of the correct procedure, and hence KBMs were common among the discussed errors. On one occasion, a nurse received on the spot training from the observer in order to enable her to reconstitute the drug docetaxel appropriately. The drug was supplied from the manufacturer in a concentrated oil-based form with an alcohol diluent. The addition of the diluent to the drug should be carried out slowly while rotating the vial carefully in order to avoid frothing and seepage of the drug through the septum (Allwood et al., 2002). The nurse was observed to push the diluent

quickly into the drug vial, resulting in significant seepage of drug which led to loss of drug volume. Therefore, it was not possible to remove the accurate volume required from the vial. Instead of ordering a new vial, the nurse was observed to proceed to add the incorrect volume of drug to an intravenous infusion bottle. Consequently, the observer intervened and asked for a replacement from the pharmacy. The nurse explained that she frequently had issues when making up docetaxel and had received no training in its reconstitution procedure, as illustrated in the following quote:

> *"We are very familiar with filling up the intravenous bottles (reconstituting cytotoxic chemotherapy and adding it to intravenous infusions) with medicines but that particular medicine (meaning docetaxel) is specifically hard to draw up and until X (observer) showed me how, I always struggled with it and when I reconstitute it, it starts to foam and a large amount spills out from the vial across the bench. (Laughing apologetically)"* **(Nurse Critical incident interview) 2**

In the second incident, the nurse failed to read the instructions on the medication administration chart carefully before administering the chemotherapy drug paclitaxel and proceeded to give the drug without administering ranitidine as premedication. Ranitidine is required to reduce side effects of paclitaxel (Allwood et al., 2002), however, the nurse was unaware of this information, as illustrated below:

> *"I don't know why I didn't look at the prescription chart or why I wasn't paying attention to administering everything on the prescription. And to tell you the truth, I don't ever remember seeing this injection (ranitidine) before. But these days, with IB (the observer) being on the ward, he is giving us new instructions and telling us things we didn't know before"* **(Nurse Critical incident interview 1)**

Nurses had difficulties with dose volume calculations as discussed during critical incident interviews. During one of the interviews, a nurse was asked to describe the procedure he followed when drawing up a 1200mg dose of cyclophosphamide from three 500mg vials. It was clear from his description that he had no knowledge of the correct procedure to calculate intravenous doses. The diluent volume he described was incorrect because cyclophosphamide powder should be dissolved in 25mL of diluent, rather than 20mL. Furthermore, the final volume he described would remove 1250mg, rather than the intended 1200mg, as illustrated below:

> *"They sent me 3 vials (500mg each) and I added 20cc of normal saline to each of the cyclophosphamide vials to dissolve the powder. I then removed the contents of two whole vials and 10cc from the third vial and this is what makes the 1200mg dose"* **(Nurse Critical incident interview 7)**

Nurses committed three violations which were discussed in the critical incident interviews. These violations were caused because it appeared that nurses commonly used a number of short cuts and improvisations during their daily tasks.

One of the female nurses described how she managed a cytotoxic spill. She noticed an intravenous drip was leaking onto the floor. Instead of discontinuing the leaking intravenous drip, she decided to get a basket to collect the spilled drug but continued infusing a patient using the open intravenous drip, as illustrated in the quote below:

> "*Then I noticed there was some water no I mean drug on the outside of the giving set. OK? and when I went to look at the drip, I found on the outside on the top of the thingy (drip septum) there was a pool of drug. At the top, it looked there was a reservoir which has a flat top and that's where I found the drug pool. I then went and got a waste bucket and placed it under the drip"* **(Nurse Critical incident interview 8)**

During the interview, it appeared that one of the senior nurses intentionally pierced the drip septum to deflate the bottle and allow the drug to flow quickly. This is contrary to best nursing practice but it seemed that nurses routinely performed this procedure in order to save time:

> *"I don't know but I have a suspicion that the sister, who works with me, deflates the drip using a needle, so she deflates the drip with a needle that she sticks in to the side of the drip. Mostly she would do that with the adriamycin, yeah, she likes to do that to... When you are using adriamycin in the drip, the drip gets too full and it flows very slowly through the giving set unless you deflate the drip bottle. I don't know but maybe she (sister working on the ward) found the drip stuck and not going through, so she decided to deflate it. Yeah that is my suspicion."* **(Nurse Critical incident interview 8)**

Another incident involved giving the patient the wrong dose of ondansetron because the nurse did not empty the contents of the medicines bag appropriately, resulting in giving the wrong dose of ondansetron. The nurse appeared to routinely empty the contents of the bag onto the patient's bed and picked up what fell out:

> *"I didn't forget that vial or anything like that, but it was at the bottom of the carrier bag and when I took out the medicines, it was hiding in a place where you can't get to it. These bags, even when you shake them empty, they still hold on to the medicine specially the ondal (ondansetron) because it is the same colour as the bag***"** **(Nurse Critical incident interview 5)**

A third violation occurred because the nurse was given instructions which he thought were not practical and explained that he intentionally altered the infusion rate of intravenous infusions:

> *"I will not adjust the rate of 5FU according to that stated because sometimes it says: Give 5FU in 30 minutes which means how much? Ha! It means 330 drops in the minute. This is impossible to count and however much I try and look at those drops; I won't be able to adjust them because my eyes won't focus. Also, the 500ml drip will never finish in 30 minutes, however hard we try!"* **(Nurse Critical incident interview 4)**

<u>Environmental factors</u>

Environmental factors were responsible for one critical incident. The nurse was busy and while preparing the dose got interrupted by one of the patients.

> *"I got distracted by the other patients on the ward and instead of halving the dose, I emptied the whole vial into the IV drip.*" **(Nurse Critical incident interview 6)**

In this instance, the observer noticed the error after it occurred and asked for a replacement prescription and replacement of drugs for the patient.

Task factors

The task of administering cytotoxic chemotherapy requires previous knowledge and preparedness. Nurses had to remember a number of steps for the safe preparation and administration of chemotherapy. One nurse described the process of giving pre-medication to patients on paclitaxel chemotherapy:

> "*Now I know that if there is a patient that requires Taxol, I will have to give pre-medication and ranitidine before giving them the medicine. I also have to wait half an hour after completing the pre-medication before giving the chemo. I will also remember how to use a 20ml syringe to dissolve the ranitidine powder. I also have to make sure that I wait between medicines and not to administer one after the other."* **(Nurse Critical incident interview 1)**

Team factors

Nurses appeared to work largely unsupervised and unsupported without ensuring their competence in the preparation and administration of complex and unfamiliar drugs. One particular nurse had to rely on help from a qualified nurse who had been previously employed at the study hospital and was accompanying a relative:

> *"A nurse came in; she was here with her aunt who was receiving chemotherapy. She had worked here before but had left the job and was just coming in as a visitor. So, I told her that my colleague hadn't arrived yet and that I was new without anyone to help. I told her I has asked the matron for help and have already inserted in all the intravenous cannulas waiting for the matron to send someone to help me. She said "let me tell you something, no one is going to come and help you… I am going to try and help you a little bit. I will start off by giving the patients their first doses and then will leave ". I agreed and she started preparing some of the doses and explained about the medicines and what they are used for and made them up and left them all on the bench for me. So, I started to look at the patient files and match them with the medicines that she prepared."* **(Nurse Critical incident interview 3)**

It was evident during critical incident interviews, that student nurses who were unqualified also worked with cytotoxics, unsupervised. One nurse who was a student, illustrated this in the below quote and explained one instance where he intentionally violated known nurse procedures.

> *"Yes, I am still studying to be a nurse and it sometimes may take people more than 5 years to complete the nursing course... I might forget to look at the file or something like that or it may be something like 5 (5fluorouracil) which comes with dexamethasone and ondal and you don't need to look at the file very much because the dose is always 1g*" **(Nurse Critical incident interview 5)**

5.6.4.4 Nurse culpability

Determination of nurse culpability revealed that five of the critical incidents were caused by system failures, and three were caused by nurse reckless behaviours (Table 5-8). The culpability of nurses with regards to the critical incidents was determined using Reason's Culpability tree (Reason, 1990). For example, during the interview for critical incident 2, the nurse revealed that she had no previous training in reconstituting docetaxel. Hence, she experienced considerable loss of the drug during the reconstitution process which resulted in her withdrawing the wrong volume. It was evident that the nurse was not intending to cause harm, did not violate known procedures, however, she was likely to repeat the error, because she was unaware of the correct procedure. Hence, this error would be classified a system error because it was caused by a failure of the organization to provide training and clear task related procedures (Figure 5-6). In contrast, during the interview where incident 1 was discussed, the nurse may be classified as behaving recklessly. The nurse admitted that she did not read the instructions and hence omitted the pre-medication required for intravenous administration of paclitaxel. Although clear procedures were not available, but it is common nursing practice to read the doctors' instructions before administering intravenous medicines. Hence, the nurse in this situation may be regarded as behaving recklessly and may be culpable for the error.

Table 5-9 Culpability of unsafe acts

Cause of Error	Critical incident	Description of Error	Pre-conditions	Culpability
Knowledge Based Mistake	1	Omitted the pre-medication for the drug Paclitaxel	Deviation from known nursing procedure Lack of training	Reckless behaviour
	2	Withdrew the wrong volume of docetaxel from the vial	Lack of training	System induced error
	3	Withdrew the wrong volume of the drug cyclophosphamide from the vial	Lack of training	System induced error
	7	Withdrew the wrong volume of the drug cyclophosphamide	Lack of training	System induced error
Lapse	6	Withdrew the wrong volume of the drug vincristine	Interruptions	System induced error
Routine Violations	4	Administered the drug 5 Fluorouracil at the wrong rate	Inappropriate procedure	System induced error
	5	Administered the wrong dose of the anti-emetic drug ondansetron	Deviation from known procedure	Reckless behaviour
	8	Inappropriate management of cytotoxic drug spill	Deviation from known nursing procedure	Reckless behaviour

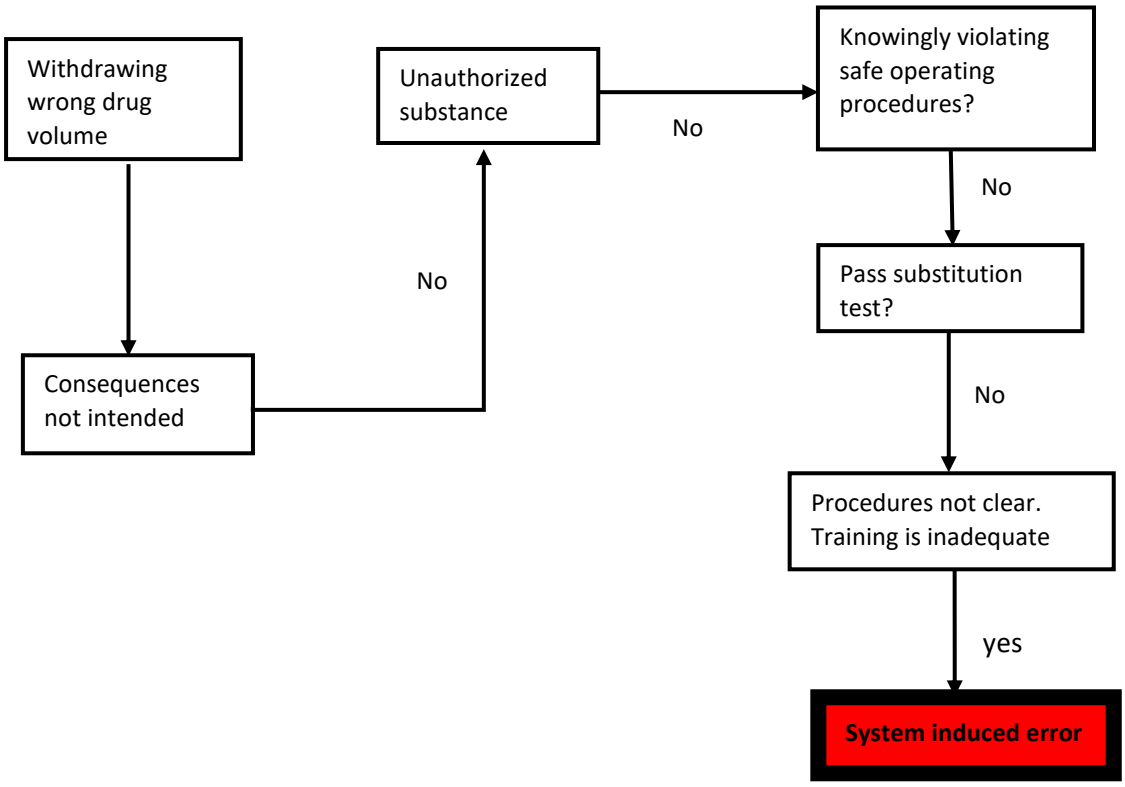


Figure 5-6 Culpability of nurse withdrawing the wrong volume of drug (critical incident 2)

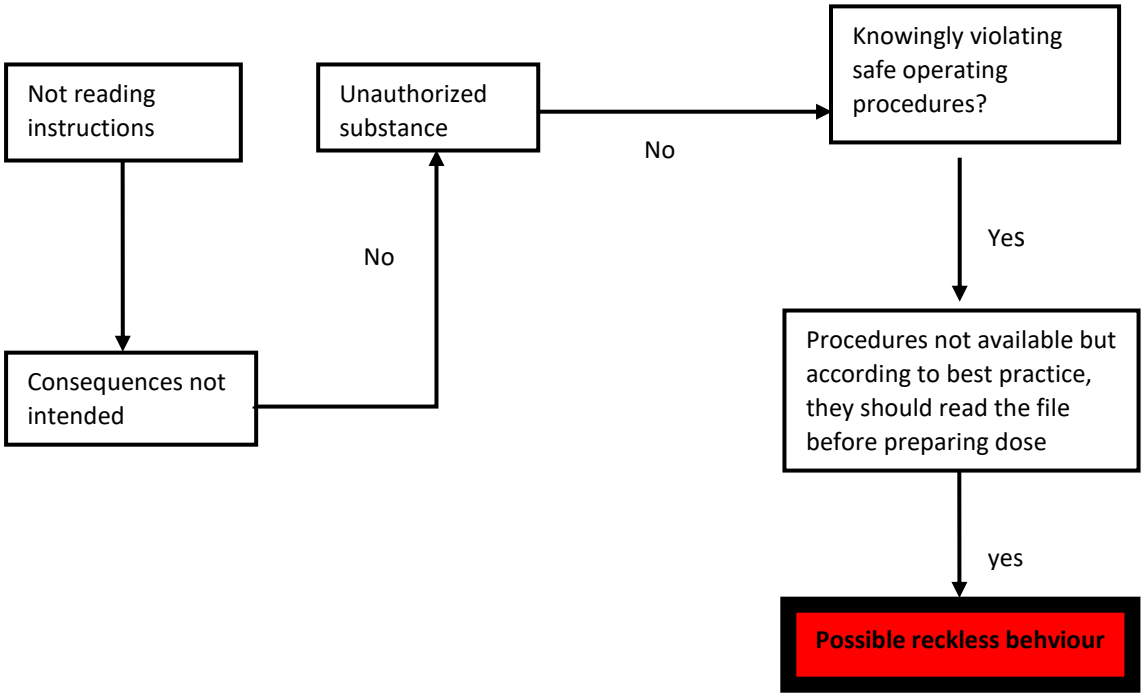


Figure 5-7 Culpability of nurse omitting drugs as a result of not reading the patient's medication file (critical incident 1)

5.7 Discussion

Findings from the current study reveal that none of the intravenous drugs observed during the study period were correctly prepared or administered. These findings are thought-provoking because they reveal that patients were at considerable risk of harm from medication errors during the study period. Each of the observed drugs were involved in at least 15 errors, caused by a number of different error and violation-provoking conditions. Observers recorded 12772 opportunities for error of which 68% were performed inaccurately. Nurses in the study hospital worked primarily unsupervised and under conditions with little access to essential equipment, training and support. Consequently, the nurses made many deviations from aseptic technique and good nursing practice, during the preparation of all observed intravenous products. In all cases, the doses were prepared without the required labeling, nurses started the administration of chemotherapy without checking the allergy status of the patient and none of the medication administration details were recorded in the patient medication file. In order to prevent errors reaching the patient, observers had to intervene and correct many manipulations including dose errors (17%), calculation errors (39%) and wrong sequence of administration (56%). It was necessary for observers to intervene in such instances, to prevent errors reaching the patient; however, a number of other errors were unpreventable because it became evident during the research that the nurses were poorly trained and had limited access to essential equipment and resources. Consequently, and in discussion with the project supervisors, the study was terminated prematurely on ethical grounds and the findings communicated to clinical managers. Hospital management decided that these findings may be used to design a targeted intervention aimed at improving nursing care and patient safety at the centre. Subsequently a multidisciplinary training team was charged with the design of a training course that included basic nursing procedures, aseptic manipulations, safety precautions and drug calculations.

The current study is, to our knowledge, the first research which has used mixed methods to investigate errors associated with the administration of cytotoxic chemotherapy. Key strengths to this study are that it included both observation and CIT to identify the types and causes of medication errors which occurred during administration of cytotoxic chemotherapy on a chemotherapy day ward, in a developing country.

Comparison of the results from the study hospital with error rates from other studies should be undertaken cautiously as data from those studies may be collected from different

sources, and may hence have different findings. For example, data from the US analysed adverse events obtained from voluntary reporting systems among paediatric cancer patients and revealed that administration errors contribute to 15% of adverse events (Rinke et al., 2007). Furthermore, comparison with similar research is complicated by more issues. Firstly, there is little published research focusing on administration errors associated with the use of cytotoxic chemotherapy. Secondly, study methodologies and settings are different. For example, Ford and colleagues (2006) analysed chemotherapy administration incident data from nurse incident reporting. In addition, most published research was conducted in western countries, where, chemotherapy preparation is undertaken under controlled conditions in centralized pharmacy units, and hence nurse preparation errors are not reported (Limat, 2001;White et al., 2014). Finally, when comparing with data that emerged from EMRO/AFRO region, further difficulties are presented. Studies have used different error taxonomies (Tavakoli-Ardakani et al., 2013), different methods (Nwozichi, 2015) and some studied the administration of oral chemotherapy which involved a different procedure to intravenous administration and is primarily undertaken by untrained care-givers (Oberoi et al., 2014). Nevertheless, findings from this study are disproportionate when compared with comparable research conducted in similar conditions. For example, findings from an Iranian study, where nurses prepared cytotoxics on open benches, reported that the error rate was 32.5% among 8322 opportunities for error involving 554 doses (Tavakoli-Ardakani et al., 2013). The findings from this Iranian study are half of what was observed in the current study.

Comparisons with findings from observational studies conducted with medicines other than cytotoxics are difficult because the published literature shows a wide range of errors (18-90%) that can be up to 100% when aseptic procedure was assessed (Barker et al., 2002a;Wirtz et al., 2003;Taxis et al., 2004;Cousins et al., 2005;Alsulami, 2013;Westbrook et al., 2011). These wide variations in reported error rates in the literature may be explained by the diverse definitions used for administration errors and the settings under study. One example, one of these differences is whether or not the researchers studied opportunities for error potentially leading to error rates more than 100%. Another example is the inclusion of nurse adherence to aseptic technique which has contributed to a greater number of medication errors (Kim et al., 2013).

This study combined observation of nursing practice on wards followed by CIT interviews focusing on specific errors. Observations of nursing practice during the study revealed tangible problems in nursing practice and revealed the frequency and type of preparation and administration errors. It was interesting to note that nurses continued to have consistent behavior despite being under observation and despite observers repeatedly intervening to correct practice and prevent errors reaching the patient. Hence, it can be inferred in this study that the Hawthorne effect had no impact because researcher observation did not appear to effect behaviour change (Pope et al., 1995). During CIT, nurses on most occasions were prompted to remember the error but on reflection gave detailed error accounts and described the error-provoking conditions.

The direct observation method is primarily used for identification of active errors (Michel, 2003) and near misses, enabling the design of targeted interventions (Kim et al., 2013). Observation is considered the gold standard in conducting research focused on identifying medication administration errors. Methods of observation have been previously validated in western countries, (Barker et al., 2002b;Taxis et al., 2003a;Wirtz et al., 2003;Keers et al., 2013b) and continue to be used by researchers in this research area (Dougherty et al., 2012;Keers et al., 2013b). However, few such studies were identified in AFRO/EMRO countries with similar healthcare settings to the Sudan (Carpenter et al., 2010). A review of 91 observation studies examining the frequency and causes of preparation and administration errors, identifies that most were conducted in western countries, with a small number of studies undertaken in Iran, Turkey and Malaysia (Keers et al., 2013b). Furthermore, studies that have emerged from the developing reveal little insight into the scope of the problem in the region. A review of 23 studies in Africa, Asia and South America identified only one observational study that investigated the re-use of syringes and inappropriate disposal of sharps in Cambodia (Carpenter et al., 2010). However, more recently, a number of studies have been published in the region (Acheampong et al., 2015;Agalu et al., 2012;Koffuor et al., 2012). For example, Agalu and colleagues (2012), investigated medication administration errors in the ICU of a large Ethiopian hospital where intravenous medicines (other than cytotoxics) are prepared by nurses on open benches on wards, similar to the setting in the current study. Although the error rate (51.8%) was less than findings from the current study, it was significantly higher than those reported in ICUs in western countries (Tissot et al., 1999).

The critical incident technique was used to interview nurses to explore specific errors and identify their causes. Analysis of these interviews, using Reason's Error Framework,

revealed that a combination latent factors and error provoking conditions were associated with the errors identified in the current study. The critical incident technique has been used recently, to identify potential causes of intravenous administration errors on a general medicine ward in the UK (Keers et al., 2015). Keers and colleagues (2015) interviewed 21 nurses from a UK NHS hospital using the critical incident technique to discuss medication administration errors involving the intravenous route. Similar to the current study, Keers and colleagues (2015) analysed findings using Reason's Error Framework which identified that most errors were KBMs with a fewer number of violations. In their study, the causes of errors were due to environmental factors such as interruptions and busy work environments. Other factors were team related issues where there was lack of supervision compounded with poor access to reliable information and resources. This confirms some of the findings from the current study, however, more factors were identified to contribute to the errors. The main factors identified were lack of resources, an absence of work procedures with poor supervision in an environment of a work culture that had poor knowledge of safety issues. Such a wide range of latent factors have been reported in a study of medication errors occurring in obstetrics in Egypt (Kandil et al., 2012). Kandil and colleagues (2012) observed medical and nursing obstetric practice during labour of 10,000 patients and found that 1976 errors occurred, of which 1222 (60%) were associated with administration of drugs. Although the setting was a labour ward rather than a chemotherapy day unit, similar latent errors were identified to those observed in the current study. The major contributing factors to errors were also poor resources, poor knowledge, team factors typified in lack of supervision and a general lack of safety culture.

5.7.1 Types of preparation and administration errors

The results from the current suggest that nurses consistently repeated the same chemotherapy administration errors regardless of which day of the week it is.

The first significant finding of the current study was the regular deviations from aseptic practices where nurses were observed to touch the surfaces of vials and intravenous fluids during all manipulations. To ensure that intravenous medicines are aseptically prepared in a manner that minimizes risks of infusate-related bacterial contamination, it is generally recommended that a" no-touch" technique should be followed (Beaney, 2010). Furthermore, observers recorded complete non-adherence to infection control practices typified by lack of hand hygiene. Nurses routinely manipulated drugs and handled patients

without washing or disinfecting hands before or after the procedure. Poor hand hygiene is typical of medical care in Sudan, although reported rates of HCW compliance (40-44%) from a tertiary care hospital (Kheder et al., 2011) and three dental units (Ahmed, 2011), are still better than the observed practices at the study hospital. More significantly, nurses in the current study seemed to only wear gloves over concern for personal safety with regards to occupational exposure to cytotoxics and appeared to regard hand hygiene as inconsequential. The nurses' apparent concern over personal safety is comparable with oncology nurses in a US hospital where hygiene practices were better post procedure (72.1%) than before clinical procedure (41.7%) (Korniewicz et al., 2010). Errors involving the aseptic technique during preparation of intravenous drugs were reported in some of the early medication safety research (Cousins et al., 2005), but recent reports show that aseptic techniques among nurses have shown improvements in comparison (Ghaleb et al., 2010). For example, an early study conducted in three hospitals across the UK, Germany and France showed that nurses in the UK hospital never washed hands or cleaned surfaces and only wiped vials in 1% of the times when preparing intravenous medicines (Cousins et al., 2005), whereas work conducted in a paediatric London hospital (Ghaleb et al., 2010), after publication of the NPSA alert 20 on safety of injectable medicines, reported a much lower rate of preparation errors, including aseptic technique errors (20.7%). In contrast, work from EMRO/AFRO countries continues to report major deviations from hand hygiene practices and aseptic procedure during preparation of cytotoxics. A study conducted on an oncology ward in Iran reported that nurses never washed hands during 93% of the procedures involved in preparation of cytotoxics (Tavakoli-Ardakani et al., 2013).

Poor hand hygiene and deviations from aseptic procedure during preparation and administration of intravenous medicines has major implications. Both are important components of infection control essential in the prevention of Hospital Acquired Infections (Allegranzi et al., 2011), prevent cross contamination from residues of cytotoxic chemotherapy (Sessink et al., 1997) and reduce the risk of infusate-related blood stream infections (Curran, 2011). The importance of hand hygiene, in particular, was highlighted by the WHO in their first global challenge "Clean Care is safer care" (Pittet et al., 2006). Non-compliance with hand hygiene is a worldwide issue, particularly in less developed countries (Pittet et al., 2009), where the burden of disease takes priority (WHO, 2004a). However, little research has been undertaken demonstrating the detrimental effect of poor infection control methods during manipulations of intravenous drugs, particularly in resource poor countries. It is generally assumed that intravenous products are prepared for immediate

use hence minimising the risk of infections. Nonetheless, bacteria have been isolated from intravenous infusions and injections prepared on wards, leading to fatal blood stream infections (Curran, 2011;Moore et al., 2005). The bacteria klebsiella pneumoniae was isolated from 65% of the glucose-containing infusions prepared by nurses on the bedside in a neonatal ICU in an Egyptian hospital (Moore et al., 2005). This contamination was linked to more than 50% of neonatal sepsis incidents at the unit. Subsequently, an intervention was designed to train nurses in the procedures and importance of hand hygiene and aseptic manipulations. A post intervention assessment after eight months showed zero levels of contamination in intravenous fluids, but outcomes on neonates were not reported (Moore et al., 2005). The potential risk for patients in the current study setting would be expected to be much higher because patients generally present with advanced disease (Hamad, 2006). Additionally, these patients are more prone to infections due to several factors; malnutrition, poor personal hygiene (Pittet et al., 2006), disease and the toxic effects of the cytotoxic chemotherapy on the bone marrow (Nurgalieva et al., 2009). Moreover, the added risk of nurse exposure to cytotoxics has been demonstrated from early studies in the UK, which showed measurable levels of cytotoxics on work surfaces where these drugs are manipulated (McDevitt et al., 1993).

Another significant finding in the current study was that nurses did not use PPE required for prevention of occupational exposure during the manipulations of cytotoxics. Nurses were not provided with cytotoxic protection gowns, goggles and in a number of instances did not wear gloves or continued to wear torn gloves. The importance of wearing PPE to reduce the potential for occupational exposure from these hazardous drugs has been highlighted by several international oncology agencies (Carrington et al., 2010b;ISOPP, 2007b;HSE, 2003). Protection from occupational exposure to cytotoxics is a shared responsibility between employers and HCWs (HSE, 2003). Although the use of PPE is important when handling cytotoxics, ultimately, they do not offer best protection against bodily contamination if the operator prepares these drugs on open benches on the wards (Fransman et al., 2004). Better protection for HCWs has been demonstrated with the use of pharmacy based cytotoxic cabinets (Mason et al., 2005) and the use of closed injection systems on wards (Clark et al., 2013). As a minimum, international safety organizations recommend that the safe handling of cytotoxics requires the use of dedicated cytotoxic cabinets (ISOPP, 2007b). Furthermore, risk scoring for the observed medicines indicated that they should all be prepared in a centralized pharmacy (Beaney, 2010).

Observations revealed frequent disregard of the written instructions on medication administration charts. Nurses on 57% of occasions used cytotoxics in the wrong sequence. Wrong sequencing of cytotoxic medication has the potential to cause serious side effects to patients. For example if vinca alkaloids are administered after antimetabolites there is an increased risk of extravasation (Allwood et al., 2002;Stanback et al., 2007). Although little evidence from published studies identified wrong sequence errors during the administration of chemotherapy, a survey of 207 chemotherapy nurses reported that sequence errors do occur during chemotherapy administration (Ulas et al., 2015). Unlike the current study, only half the respondents reported being involved in sequence errors which were caused by heavy workload (Ulas et al., 2015).

Labelling of the medicines, in the current study, was performed inadequately on all occasions. Ambiguous and poor labelling is considered a source of error associated with cytotoxics (Franklin et al., 2014). But on most occasions the labelling is performed in a centralized pharmacy unit or from manufacturers (Limat, 2001). Inadequate labelling of intravenous drugs prepared on wards may be considered an error (Franklin et al., 2009). Moreover, appropriate labelling is essential, particularly in the study hospital where the intravenous products are prepared beforehand and left on the patient bed to be administered later (Beaney, 2010).

Other observed errors were dose errors (17%), wrong administration rate (40%) and failure to carry out an independent second check (92-95%) during intravenous medicine preparation. Dose errors and wrong rates of administration represent two of the three common error types reported in the literature, the third being wrong administration technique (Keers et al., 2013b). They are considered clinical errors with the potential to cause serious harm to patients (Westbrook et al., 2011) and hence required intervention and correction by the data collectors, in the current study, before they were administered to patients.

5.7.2 Categories of active failures

Active failures occurred due to KBMs linked to lack of knowledge and training in the use of intravenous medicines in general and cytotoxics specifically. Unlike the evidence in the literature, KBMs occurred when nurses were working in familiar environments on routine tasks, with very little evidence of distractions. KBMs are commonly reported in medication error literature and can contribute to 79% of medication administration errors when

working with unfamiliar drugs, complex technologies and drawing up small dose volumes (Taxis et al., 2003a). It can be argued that although KBMs are commonly associated with non-routine tasks, poorly trained HCWs can be involved in such mistakes when performing routine tasks because they lack the necessary skills and knowledge and are constantly required to identify solutions (McDowell et al., 2009). Findings from the study hospital identified only one slip that was associated with interruptions. However, data from medication error research show they are more common. A review of 55 administration error studies revealed that slips and lapses due to interruptions, high workload and confusion of "look-alike, sound-alike" medicines were reported in 53.7% of the studies (Keers et al., 2013a). Violations seemed to be common in the hospital under study because three of the critical incidents discussed in the interviews were attributed to a violation. For example, a nurse admitted that he deliberately flouted instructions on the infusion rate of intravenous medicines because he had no access to an infusion pump that allows him to accurately adjust the rate of infusions. Violations are common medication administration errors and are associated with poor knowledge, poorly designed protocols, lack of staff and insufficient supervision (Keers et al., 2013a). In general, violations occur from system errors where task-related guidelines are either unsatisfactory or inappropriately implemented and monitored (McDowell et al., 2009).

5.7.3 Error-provoking conditions

Nurse interviews revealed a number of interlinked factors which provided the environment that provoked the observed errors and violations. The majority of preparation errors resulted from the lack of resources and working guidelines pertinent to the appropriate preparation and administration of intravenous products. Nurses in the current study were observed to work under conditions where there was limited access to equipment necessary for their daily tasks. For example, one of the nurses explained that she had a daily quota of three pairs of gloves, regardless of the workload. This meant that nurses had no option but to re-use gloves and may continue to wear gloves even when torn. Moreover, nurses had little access to pens used for labelling and no access to calculators essential for performing mathematical calculation required for deciding dose volumes and adjusting infusion rates.

Although unrelated to the critical incidents discussed, most of the nurses admitted that they routinely washed and re-used syringes to reconstitute medicines or add medicines to intravenous fluids which are already being infused to patients. They resorted to this

measure because there were frequent stock shortages of syringes in the pharmacy. Medicine and medical equipment stock shortages are common in Sudan and some essential medicines can be out of stock for up to 42 days (Cheraghali et al., 2009). In general, the re-use of injecting equipment in medical practices is well documented and has been implicated in 20-40% of HIV in Africa and in the spread of malaria, Lassa virus, hepatitis B and C viruses (Simonsen et al., 1999;Schmid et al., 2004;Hauri et al., 2003). Estimates of unsafe injection use in Africa is almost 20%, presenting a source of significant public health risk (Hauri et al., 2003). Interventions proposed by the WHO require national and organization level commitment and include promoting safe injection use through campaigns, effecting behaviour change and provision of disposable syringes (Kermode, 2004). Although the single use of disposable syringes has become a law in many developing countries the WHO recognizes the challenges of this because many hospitals have limited budgets (Kermode, 2004). Working under such limited resources means that nurses will have difficulty complying with good nursing practice essential for patient safety (Aveling et al., 2013).

Nurses had no knowledge of whether national or hospital based policies and procedures were used at the study hospital. They stated that they observed the practice of senior colleagues to guide their daily work. This was confirmed in the current study in that 7 of the 8 critical incidents were associated with poor nursing procedures. In the absence of task related policies and procedures, it was reasonable to expect a small degree of violations during the study, but the magnitude of habitual violations was unanticipated. Half the nurses interviewed admitted they routinely violated known nursing practices. For example, one nurse explained that although nurses were aware of the risk of bacterial contamination they routinely spiked infusion bottles to allow the intravenous infusion to flow faster. Another nurse admitted that he may not read the prescription details before preparing the medicines. Inadequate procedures have been linked to medication errors and violations of safe medication practices (Taxis et al., 2003a). An early survey of 45 small cancer units, conducted in the North East of England in 1993, revealed that nurses in most hospitals received no training and had no written instructions on the safe administration of chemotherapy (Woodman et al., 1996). Without the presence of task related policies and procedures it would be difficult to implement and audit safe practices (Cousins et al., 2005). Written policies and procedures are necessary for standardization of practice and the delivery of safe cancer care (Jacobson et al., 2009). However, the presence of procedures in themselves is not sufficient to ensure that medical care is safe (Cousins et al., 2005). In the context of cancer therapy, the development of task related policies and procedures should

be accompanied by training of HCWs and annual assessments as an assurance of competency (Pan London, 2011).

Findings from the current study revealed that nurses received little formal training before or during their work in the study hospital. For example, a nurse who had no previous experience in cancer care was working unsupported with no induction or training on her second day of working. Training of HCWs who are charged with preparing and administering cytotoxics is essential for safe handling and delivery of safe medical care (Woodman et al., 1996;Schulmeister, 2006) and is currently a requirement in a number of countries (Pan London, 2011;Jacobson et al., 2009). Nurses require knowledge and training to guide them in problem solving, judgement and diagnosis of patient issues, the lack of which leads to errors in planning and execution of essential patient care tasks (McDowell et al., 2009). Moreover, nurses act as the last barrier against errors in the medication process (Walrath et al., 2008) and without training, they are ill-equipped to identify and intercept errors before they reach the patient. National or local policies regarding nurse education have a positive impact on patient safety and nurse confidence and competence. For example, in the UK, subsequent to development and implementation of a Department of Health policy, improvements in nurse knowledge and confidence have been reported (Verity et al., 2008). A questionnaire among 255 nurses from 26 cancer hospitals in London revealed that more than 80% have received formal education and 86% have confidence in undertaking their assigned tasks (Verity et al., 2008).

The importance of the latent factors, typified in poor resources, absence of training and policies and procedures as discussed by nurses, was confirmed in the findings of the current study. Nurses seemed to lack knowledge about performing a number of tasks in five of the critical incidents discussed in nurse interviews. An example was the inaccurate calculations which were reported in 39% of the observations. During the critical incident interviews, all the nurses admitted that they received no formal training in calculations and one nurse failed to accurately perform a dose calculation, during critical incident interviews. Calculation errors have been commonly reported in medication administration (Keers et al., 2013a) but a review of the literature on medication administration errors showed no association with mathematical skills (Wright, 2010). Wright (2010) reviewed 33 studies and 5 reviews on nursing administration errors which identified no evidence of a link between administration errors and nurses' calculation and mathematical skill. Nevertheless, calculation skills are important because they are necessary for the accurate preparation

and administration of medicines (Lavery, 2011). Training in calculation skills are necessary for nurses working at the study hospital because they were identified as lacking.

During three interviews, nurses admitted that they routinely omitted reading the prescription before preparing the drugs. This was confirmed in the observation study where reading the prescription was not performed in 41% of the observations. This omission may be linked to a culture of short cuts evident from nurses' accounts where they intentionally violated written instructions. An explanation for this behaviour may be inferred from the uncontrolled work environment where nurses compensated for the defective conditions by adopting a culture of "making do" (Dixon-Woods, 2010). Nurses are responsible for ensuring that the prescribed medicines are appropriate for the patient and that the dispensed medicine matches the prescription (NPSA, 2010b). Thus, reading instructions is vital and failing to do so may be considered a violation which has implications for patient safety and nurse culpability (Weiner et al., 2008).

It was evident from the nurses' interviews in this study that team work was inadequate, because in five of the critical incidents supervision was apparently lacking. A student nurse and a new nurse were allowed to work unsupervised throughout the study period. Supervision of nurses during administration of cytotoxics is a necessary requirement identified by standards published by the American Society of Clinical Oncology (ASCO, 2004) and the Clinical Oncological Society of Australia (Carrington et al., 2010b). In UK hospitals a register of competent nurses who can work unsupervised is kept (Pan London, 2011). Supervisory support is of particular importance to new and novice staff who have no previous experience (Dougherty et al., 2012) because they lack the problem solving skills necessary to ensure patient safety during patient care (Reid-Searl et al., 2010). Poor supervision has been implicated in errors in chemotherapy and non-chemotherapy associated administration errors (Keers et al., 2013a;Mehta et al., 1998;Anselmi et al., 2007).

5.7.4 Nurse culpability

In view of the many system and organizational shortcomings identified from nurses' interviews, unsafe acts were analysed using Reason's culpability tree in order to ascertain whether the nurses were culpable for the errors (Reason, 1997).

Unsafe acts caused by lack of procedures, training and unfavourable conditions and are likely to be repeated are due to system errors (Reason, 1997). Nurses on these occasions

are not culpable for the unsafe acts because they are acting in the best interest of the patient (Khatri et al., 2009). On one of the incidents discussed during the critical incident interviews, the nurse adjusted the rate of intravenous fluid, inaccurately, because he perceived it was not possible for a 500ml intravenous infusion to take place over 30 minutes.

Errors where nurses violated standard nursing procedure would make the nurse culpable because it was reckless behaviour (Reason, 1997). On the occasions where the nurse "spiked" the septum of an infusion bottle or routinely removed drugs by shaking empty the bags, a violation of common nursing procedure was apparent.

5.7.5 Interventions identified from medication error literature

In general interventions to correct medication administration errors, are either targeted at nurse training or involved the introduction of automation (Berdot et al., 2015). A recent review of such interventional studies revealed that many had limitations which included bias caused by lack of blinding to outcome assessment. The interventions included simulated training, pharmacist led training and automated dispensing systems. However, the authors reported that there was no evidence on the impact of interventions on improving administration errors (Berdot et al., 2015). Nevertheless, safety agencies have recommended the use of automated systems and more importantly nurse training as a prerequisite to undertaking the preparation and administration of cytotoxics (NPSA, 2010b). Nurse training is essential in any healthcare setting and particularly when handling cytotoxics which have the potential to harm both the HCW and patient. Moreover, training has been reported as an essential process to increase nurse confidence when dealing with these drugs (Verity et al., 2008). Nurses revealed that educational preparedness and the presence of role models dispelled fears associated with cytotoxics (Verity et al., 2008). Culture change was possible in healthcare institutions through a multiple modality approach consisting of five components; system change, training and education, evaluation and feedback, reminders at the work place and institutional safety culture (Allegranzi et al., 2007). The hand hygiene practices interventions suggested by the WHO in their "Clean Care is safer care" have been implemented successfully in a healthcare setting in Sudan (Ahmed, 2011). One of the key factors driving the implementation of the project included enforcing leadership roles using motivation and financial incentives. Although the project author

assessed change after three weeks of implementation, there was more than 100% improvement in hand hygiene from 44% to 94% (Ahmed, 2011).

There are no studies evaluating interventions targeting nurse calculation skills for dose and rate of infusion errors during medication administration (Berdot et al., 2015). Since nurses at the study hospital had no access to calculators, and limited formal knowledge in performing those mathematical skills, errors can be expected. One potential intervention to address wrong dose errors identified in 17% of observations in the study hospital would be the referral of all drug manipulations to pharmacy. A UK study in an NHS hospital showed that pharmacy prefilled injections and infusions were 17 times more likely, to have the correct intended concentration of drug, compared to those prepared by nurses on the ward (Adapa et al., 2012).

5.7.6 Limitations of the current study

There are several limitations to the methods used in the current study. First, medication error data were collected via observation methods with its associated limitations, principally the Hawthorne effect (observer effect on changing the behaviour of people when observed) and observer error. However, evidence from medication error research has shown that this had no significant effect on errors (Dean et al., 2001). Second, to obtain information on the causes of medication errors it was necessary to interview nurses, which meant that data were not generalizable. However, this was not the intention of the study and the exercise revealed that causes of errors are common and shared (Smith, 1998). Both methods have been used extensively in medication administration error research (Keers et al., 2013a;Keers et al., 2013b). Furthermore, combining both methods provided a more comprehensive insight into the aims of the current study. Third, both the number of nurses and drugs observed was small in relation to some medication error studies (Ford et al., 2006) but sample sizes of 100-1000 have been used in previous work (Keers et al., 2013b). Moreover, the sample size included in the current work was sufficient to collect worthwhile data. The initial plan was to collect data over a longer period, however the study was terminated due to ethical considerations. It would have been unacceptable to continue recording errors when it had been identified that both nurses and patients were at considerable risk from the factors associated with cytotoxic chemotherapy administration.

5.8 Conclusions

In conclusion, findings from the current study indicated that the quality of healthcare delivery in the study hospital was unsafe. Comparisons with studies conducted in similar settings show that the error rate at the study hospital was considerably higher. Although none of the preventable errors reached the patient during the study, this was because of interventions from the research team observers. Therefore, this suggests that such errors are likely to occur during normal routine work when it is unlikely that other HCWs would be present to correct or intervene in such errors. Chemotherapy errors can be very serious (Cousins et al., 1994) and have been targeted as a priority by the UK NHS (NPSA, 2010a). The combination of poor nursing technique and the absence of formal guidance mean that errors are likely to continue to occur, jeopardizing patient safety, unless there is commitment to improved of care. In general, conscience safe practice may be important in reduction of errors, but will not guard against the occurrence of errors, and hence a redesign of the medication administration process in necessary (Merry et al., 2011).

CHAPTER SIX

6 FINAL DISCUSSION

6.1 Overview of Patient safety at a major cancer centre in Sudan

The current study has revealed that patients receiving chemotherapy within the local cancer unit are at an unacceptable risk of harm as a direct result of the way medicines are prescribed and administered. This stems from a lack of patient safety culture within the organization. Ensuring that patient safety is seen as the priority in health care institutions in the Sudan continues to be a major challenge. Health policy in the country focuses on the need to provide equitable access to care (FMoH, 2007a) but it is the patients right that care is of sufficient quality and does not cause harm (Edwards, 2005). Harm from iatrogenic injury is not limited to any one country because evidence from both developed countries (Kohn, 2000) and developing countries has shown that healthcare is associated with significant harm to patients and is mostly avoidable (Wilson et al., 2012). The WHO defines safety as the prevention of healthcare related errors and adverse events to patients (WHO, 2015). Research in patient safety has been heightened in the last decades in response to evidence of healthcare associated harm from high income countries (Kohn, 2000) and has shown that incidents associated with medicines play a significant role (Bates, 1999). However, important research gaps still exist; in particular, there is a lack of evidence about healthcare systems in developing countries, especially with regards to medication errors. This current research programme is among the first to try and address this lack of knowledge and has identified serious issues relating to a lack of patient safety culture manifesting in unsafe practice that has the potential to harm patients.

During the course of this work, three separate studies were conducted. The first examined safety culture at a major cancer centre in Sudan, while the second and third studies investigated the nature, frequency and causes of prescribing errors and errors associated with preparation and administration of cytotoxics.

During the course of the study, observations, in depth interviews and focus group discussions were conducted with a total of 62 HCWs. Members from both the medical and nursing teams were the primary focus of this study, but they provided an indication of the prevailing culture at the cancer centre.

Frequent and serious medication errors were identified during two stages of the chemotherapy process; prescribing and administration, some of which had the potential to cause serious harm if not death. Doctors and nurses of all grades made errors, so deficiencies in experience and knowledge can only partially explain the observed behaviour. For example, the frequency and severity of prescribing errors in the current study were not

associated with the doctor's level of experience, whereas some reports in the literature have shown that junior doctors as responsible for most errors (Dean et al., 2002a). The rate of administration errors was considerably high and the majority of prescribing errors (88%) would have resulted in serious harm to patients had pharmacists not intervened to rectify them.

Interview and focus group participants reported violations and described errors that had resulted in patients requiring hospitalisation and extensive medical intervention. They also described punitive actions by both senior clinical staff and managers in response to incidents. Participants reported poor working environments with a lack of infrastructure that often resulted in healthcare staff working in under-resourced environments that routinely undermined error defences placing patients and HCWs at increased risk of harm. One example was the lack of PPE essential for protecting HCWs from occupational exposure to cytotoxics.

Participant's accounts indicated that they felt largely unsupported by management and senior members of the healthcare team and frequently ill-equipped with the necessary skills and training required to deliver high quality care for cancer patients. This was evident from the analysis of the psychological basis of the various unsafe acts, included in the critical interviews. For example, most of the unsafe acts discussed in the critical incident interviews associated with administration errors, were due to violations or KBMs, which is contrary to those reported in the literature where skill-based errors such as slips and lapses are more common (Keers et al., 2013a). The violations may be linked to poor staff morale, poor supervision and failure to reward compliance or sanction non-compliance (Reason, 1995). The presence of a relatively large proportion of KBMs in relation to skill based errors can be explained by the levels of human performance; skill based, rule based and knowledge based. These hierarchical levels reflect decreasing familiarity with the task and the situation (Rasmussen, 1983). Knowledge-based performance occurs in situations which are novel to the HCW, requiring problem-solving and reasoning to decide a course of action. Hence the KBMs identified in the current study may be associated with limitations of HCWs in problem solving and may reflect inadequate training and preparedness to achieve task related goals.

Staff working at the study hospital displayed unhelpful professional boundaries and poor team working which, as reported by others, represents a clear threat to patient safety (Sexton et al., 2000). For example, four of the ten prescribing errors discussed in the critical incident interviews were associated with team hierarchies where junior staff are told what

to do and felt unable to ask questions even when they were concerned that the action was wrong.

Similar to the findings of the current study, these issues have been reported in relation to patient safety in literature emerging from developing countries (Aveling et al., 2015). A qualitative study involving in depth-interviews with over 50 HCWs from two different East African countries revealed that staff attributed their failure to deliver safe care to poor team relationships, lack of resources, and inadequate training (Aveling et al., 2015).

6.1.1 Medication safety incidents

In order to appreciate the patient safety issues associated with provision of care at the cancer centre, it was necessary to have an insight into the activities and processes practiced by HCWs during the prescribing, preparation and administration of cytotoxic chemotherapy. Accordingly, ethnographic interviews were used to map these processes prior to undertaking the studies described in chapters 4 and 5. Findings from these qualitative studies revealed inconsistencies among HCWs in the manner in which the care process was conducted. Subsequent work, in the current study, identified a number of patient safety incidents associated with prescribing and administration of cytotoxics. Although all of the incidents identified, were prevented and did not reach the patient, they provided an indication of the patient safety systems at the cancer centre. It has been proposed that although incidents that result in harm reveal the patient safety risk in the system, identification of prevented incidents reveal the inherent flaws in that system (Reason, 1997). This assumption confirms that identification of prevented incidents enables the systematic analysis of adverse event causation and reveals the weaknesses *"holes"* in the defence layers against patient harm (Reason, 2000).

6.1.1.1 Prescription incidents

The prevented prescribing error rate was 10% (chapter 4), of which more than three quarters had the potential to cause serious patient harm. In line with studies in similar settings (Alsulami, 2013;Mathaiyan et al., 2015), this thesis revealed that hand-written prescriptions were vulnerable to errors. Evidence from the literature has recognised that hand written prescriptions depend on the prescriber's individual ability to recall the many elements required to complete a prescription for chemotherapy. This is likely to result in individual doctor's interpretation of complex treatment regimens, transcription errors from treatment plans and omission errors (Dinning, 2005). Standardisation of prescribing using

standard prescription templates can result in a significant decrease in prescribing errors (Ranchon et al., 2012). However, the potential harm associated with the errors identified in the current study were not comparable to similar published research. For example, in an Indian cancer hospital, researchers reported the most common errors were omissions with very low potential to cause patient harm (Mathaiyan et al., 2015). Mathaiyan and colleagues (2015) analysed 1500 cytotoxic chemotherapy prescriptions issued to cancer patients in a day unit of a cancer centre in India. The error rate was over 280% but errors were mostly associated with omissions of patient data, the use of brand names and abbreviations. Unlike the findings of the current study, only 12% of errors had the potential to cause patient harm (Mathaiyan et al., 2015).

6.1.1.2 Preparation and administration incidents

Findings from the research presented in this thesis reveal there are substantial flaws in the system followed in the preparation and administration of cytotoxics, exposing both patients and HCWs to unjustified risks. None of the medicines observed were prepared or administered correctly, therefore the error rate for preparation and administration of cytotoxics was 100%. Even though, this finding raises considerable concern, it was more disconcerting that HCWs involved seemed to have no knowledge of appropriate procedures and hence errors were repeated consistently. All the errors which had the potential to harm patients were intercepted and corrected by the observers. This may imply that during normal working days, errors can go undetected, potentially leading to patient harm. These findings are not corroborated by the evidence in the literature, from both high income countries (Keers et al., 2013b) and developing countries(Alsulami, 2013). A review of 91 studies conducted in high income countries revealed that 53% of intravenous doses were involved in an error (Keers et al.). Whereas, another review of administration error studies undertaken in countries from the EMRO region revealed that up to 50% of medicines administered were involved in errors (Alsulami, 2013).

6.1.1.3 Factors influencing errors

Respondents, when prompted were able to provide detailed accounts of the working environment at the time errors occurred. Active failures identified in the current study were influenced by and interacted with a number of latent failures. Participants reported violations and described slips and mistakes that occurred in their workplace. The causes of these active failure were complicated by an interplay of multiple factors involving a substantial lack of infrastructure necessary for the provision of basic medical care,

inadequate organizational design, adverse environmental factors, task factors, patient, individual HCW and team factors. For example, nurses were not provided with adequate resources required for the safe preparation of hazardous intravenous cytotoxic chemotherapy. There were consistent shortages of gloves and syringes which meant that nurses, re-used gloves and re-used syringes, placing both themselves and the patient at considerable safety risks. The current research identified that professional boundaries and poor team work, contributed to errors, an issue previously identified to affect other healthcare organizations (Sexton et al., 2000). A survey of more than 1,000 nursing and medical staff from 12 hospitals across five countries (3 European, USA and Israel), working in surgical theatres and ICUs revealed that half of staff felt that team hierarchies prevented disclosure of errors (Sexton et al., 2000). Participants, in the current study, described actions by senior members of staff and management which they considered threatening and demeaning. Structures of authority and accountability were described by staff as not always transparent and hence functioning inadequately. Participants' accounts demonstrated that they were largely unsupported by management and senior members of the healthcare team and frequently felt they did not have the necessary skills and training required to deliver high quality care for cancer patients. For example, a junior doctor was given the task of prescribing cytotoxic chemotherapy with little previous knowledge and with no access to information about the names of drugs and the supportive therapy required. Consequently, there was low morale among a number of participants and fear of punishment, if they were found to be involved in errors. HCWs were working in conditions where a number of elements essential for ensuring both their safety and that of patients were absent.

The current research demonstrates that there are some factors common to other hospitals in high income countries. Although the nature of hazards that threaten patient safety are not entirely similar (Bates et al., 2009), it is likely that the origins and solutions to these issues is shared whether it is a developing country or developed country (Aveling et al., 2013). Although detrimental effects on patient safety could in part be attributed to poor resources, the study hospital, shared similar problems with other healthcare institutions, rooted in human factors, resources, culture and behaviour (Dixon-Woods, 2010).

6.1.2 Patient safety culture at the cancer centre

During the course of this study focus groups using the patient safety culture tool (MaPSaF), elicited the views of members from the nursing, pharmacy and medical teams about the

safety culture at the cancer centre. This specific study was important, because there was a need to identify the safety systems at the study hospital. However, health care institutions in developing countries, including the study hospital, are likely to have inadequate information systems (WHO, 2010), and hence conducting quantitative methods such as the use of questionnaires would have produced limited results. Moreover, this study provided the opportunity to benchmark the safety systems at the study hospital against external organizations and to identify areas of concern. Finally, previous research has shown that the act of undertaking a safety culture assessment in itself improves the awareness of HCWs about patient safety issues (Nieva et al., 2003). Focus group participants consistently rated the ten dimensions of the MaPSaF at the lower levels because, according to their accounts, there was little priority given to quality, no investment in patient safety training and poor communication when an error occurred. In contrast, research in other countries in the AFRO/EMRO region (Mayeng et al., 2015;Webair et al., 2015) rated some dimensions of patient safety culture as 'mostly acceptable' (Mayeng et al., 2015;Webair et al., 2015). A study in South Africa, where healthcare resources are inadequate and medical errors are common, was undertaken using a modified a questionnaire version of the MaPSaF. The questionnaire was distributed among 200 HCWs from different teams and achieved a 72% response rate. Unlike the current study, most respondents rated the patient safety culture at their hospital as acceptable (42.4%), good or excellent (43.1%) with a minority rating the safety culture as poor or failing (14.6%). These differences in perception between healthcare staff in South Africa and Sudan, may be attributed to the presence of incident reporting systems at the South African study (Mayeng et al., 2015).

Poor resources, inadequate organizational systems and unsafe environments have an undeniable effect on patient safety. Reason (1998) argued that system failures act as traps which attract HCWs into repeated patterns of unsafe acts. The presence of these traps is necessary for erroneous behaviour but does not provide sufficient explanation for the underlying motive. It is argued that the motive for these errors is the poor safety culture of the healthcare institution (Reason, 1998). Safety culture is fundamental in providing safe health care (Gandhi et al., 2016) and is said to exist when HCWs are informed about the level of safety, engaged in reporting errors which are then managed in a just manner. The healthcare team hierarchies must be flexible and have the ability to adapt and re-configure when dealing with errors and staff should learn from errors, make appropriate conclusions and implement changes to prevent those errors in the future (Reason, 1997).

HCWs from the three professions, in the current study, were aware that errors occurred but they generally viewed them as isolated incidents without the realisation of the breadth of the problem. Formal incident reporting systems were seemingly absent according to respondents' accounts and when incidents were reported, they followed a sporadic and unsystematic manner. The absence of a reporting system meant that HCWs were not in a position to learn from their own errors or those of their peers. HCWs were uninformed about errors and error prone-situations and hence errors were repeated by all staff regardless of the level of experience or education. Many of the doctors and nurses were ultimately working hard to deliver highly complex medical care to cancer patients, but it was apparent that many had come to think of medical errors as inevitable and potentially un-manageable. More significantly, common mistakes that stemmed from small incremental deviations from safe practice become normal practice (Hughes et al., 2010). This inevitability led to the normalisation of errors where common mistakes became acceptable, and consequently such incidents were considered not worthy of reporting (Dixon-Woods, 2010). This deviant behaviour is a considerable potential risk to patient safety (Ramsay et al., 2014), as confirmed by the high proportion of potential harm associated with prescribing errors in one of the studies conducted as part of this research (Chapter 4). Similar findings were described in a report by Sir Francis (2013) relating to poor quality at the Mid Staffordshire NHS Trust (MSFT Public Inquiry, 2013), as:

> *"a culture of habituation and passivity"* (Mid Staffordshire NHS Foundation Trust Public Inquiry 2013 pp26)

Findings from this study showed that an informed culture where errors are reported and learned from was absent. These findings are similar to previous research conducted in the AFRO region of the WHO. A questionnaire survey was conducted among 128 nurses in an oncology hospital in Nigeria (Nwozichi, 2015) which identified that although nearly 90% of nurses had been involved in cytotoxic chemotherapy errors, none were reported to the national or hospital incident reporting system (Nwozichi, 2015).

Moreover, findings from the current study revealed that errors were generally regarded as the responsibility of the individual involved and reporting only occurred informally and in some instances these were either ignored or the person involved reported and then punished by the organization. Furthermore, it was revealed that fear of blame was prominent and tangible as respondents explained that disclosure of errors could damage

professional reputations and lead to retribution. This may also explain the difficulty in recruiting participants to the study.

Participants almost invariably ascribed the causes of errors to other people e.g. nurses, junior doctors or managers etc. When seeking to manage errors, respondents found it logical to concentrate on people management through re-training, exhortations to be careful next time and increasing financial incentives. It was evident that HCWs at the study hospital viewed people as capable of choosing between safe and unsafe acts, thus error management was more of a reactive set of activities which focused on the active failure rather than the latent conditions. One reason for this, could be "the fundamental attribution error" where managers and senior medical staff identify human actions, rather than situational or organizational contributions as the cause of errors (Reason, 1997). Individuals are seen as having the will and ability to prevent errors. Consequently, errors are managed with warnings, threats and sanctions which have little or no effect upon the error-producing situations. Hence, errors continue and HCWs are seen as deliberately flouting authority, leading to a *"blame cycle"* (Reason, 1997). It is these factors that combine and drive the blame cycle (Figure 6-1). In the presence of the overwhelming culture of blame, a just culture was absent. The presence of a blame culture was documented as a significant barrier to error reporting in western countries (Aronson, 2009) and countries from the AFRO/EMRO region (Mansouri et al., 2014). There has also been documented evidence of high punitive actions in response to errors (Aboul-Fotouh et al., 2012). An Egyptian survey, using the AHRQ questionnaire, of patient safety culture among more than 500 HCWs from nursing, pharmacy and medical teams, revealed that 80% of participants regarded punitive action to errors as an issue, resulting in perhaps the relatively low score (33%) of reporting incidents. Furthermore, patient safety scores for junior members of staff were significantly lower than those of senior members (Aboul-Fotouh et al., 2012). Furthermore, HCWs in the current study revealed that they felt unable to intervene if they observed their senior peers making an error. The participants in this study reported incidents where strict team hierarchies were evident. In a number of incidents, the study participants felt helpless when observing errors or when forced into erroneous behaviour by senior members of their team. Furthermore, they considered that teamwork within their unit and across units was not conducive to patient safety.

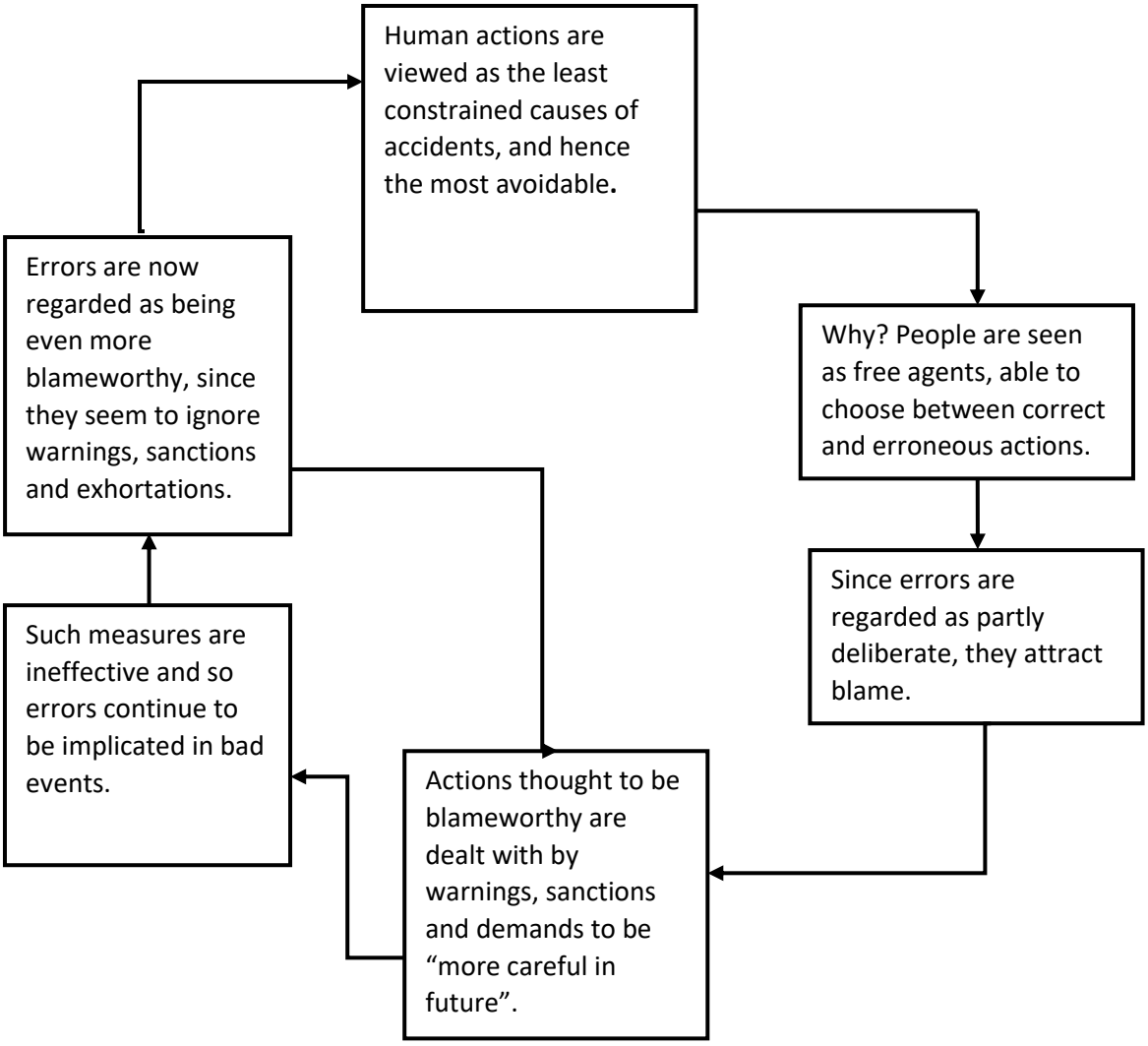


Figure 6-1 The elements of the blame cycle (Reason 1997 pp 128)

6.2 The impact of errors on cancer patients

The cost implications in providing additional care to patients affected by medical errors is substantial (Pronovost et al., 2012;Ranchon et al., 2011). A study conducted in a 1200 bed hospital in France, analysed more than 6,000 cytotoxic chemotherapy prescriptions for errors, over a course of 12 months. The authors identified an error rate of 5.2%, which was in line with other previously published studies (Gandhi et al., 2003). They estimated that patients affected by medication errors can require up to 210 extra days of hospitalisation, which may cost nearly 100,000 Euros to cover hospitalisation and additional drug interventions to manage harm associated with those errors (Ranchon et al., 2011). In Sudan, the cost of extra care would likely be a burden on the patient, because once discharged

from the cancer hospital, most community and secondary care would incur out of pocket expenditure, which may in itself act as a barrier to care seeking (Kronfol, 2012).

Furthermore, patients receiving cytotoxic chemotherapy are at an increased risk for suffering harm due to medication errors due to the inherent toxicity of the medicines used. The National Cancer Institute Common Toxicity Criteria, lists 750 ADRs caused by the use of cytotoxics some of which may require hospitalisation or have the potential to result in death (Trotti et al., 2003). This is of particular concern since, at the time of this study, in a country of nearly 2,000,000 square kilometres, (FMoH, 2007a) there were only two institutions where Sudanese patients could access cancer care, one of which was the study site (Saeed et al., 2014). This meant that patients would travel to the city to receive treatment and most likely return to their homes which could be isolated with poor access to medical care (Ibrahim et al., 2011). It is likely that patients suffering ADEs following a medication error might not have access to or might not seek medical care, partly due to a low literacy rate of 35% (Hammoud, 2006) and poor health education (FMoH, 2007a). Evidence in maternal health has shown that care seeking behaviour in Sudanese patients is dependent on level of education (Ibnouf et al., 2007) and poor health outcomes are positively linked to illiteracy (Ali et al., 2011). The outcome of medication errors associated with cytotoxic chemotherapy, in Sudan, is unknown, because evidence has shown that medical records are deficient in cases of death and hospital admissions (WHO, 2010;Abdalla et al., 2007). Hence, it is likely that harm as a result of a medication error associated with cytotoxic chemotherapy in the setting of the current study, would not be reported. Patients affected are likely to have little access to healthcare and may suffer serious consequences to their health.

6.3 Implications for practice

This thesis has identified major obstacles to patient safety which underscore the need for a multi-faceted approach that targets active failures, organizational deficiencies and institutional infrastructure. In low income countries, the decision-making process during planning quality improvements, has to be based on sound local strategies that optimise the injection of new resources (Bengoa et al., 2006). However, there is little research in similar settings that investigate the effect of the different interventions which have been shown to be effective in high income countries (Rowe et al., 2005).

It is clear that deficiencies existed in the quality of healthcare provided at the cancer centre under study. More worryingly, HCWs looked to others to guide them in their daily work. Since the prevalent norms were seemingly well below the expected standards of quality care, this attitude could lead to important negative consequences (Donabedian, 2002). Substandard levels of care will become the norm and HCWs will no longer be able to distinguish practices that have the potential to cause AEs (Donabedian, 2002).

However, it has been recognised that deficiencies in personal performance are permitted by a defective system (Donabedian, 2002). Health systems have the ultimate responsibility to make care safer for patients because this is both a public health priority and a human rights issue (Wilson et al., 2012). The role of leadership in providing safer healthcare systems is key to its success. In the report "To err is human- Building safer health systems" the authors stated:

> *"The committee believes safety must be an explicit organizational goal that is demonstrated by clear organizational leadership and professional support as seen by the involvement of governing boards, management, and clinical leadership" (Kohn 2000 p161)*

The need for overall improvement cannot be contested and to undertake this effort, one needs to adopt a robust evidence based model as a framework. Avedis Donabedian has proposed a basic framework in which to consider quality improvement efforts. He proposed that quality can be classified under three categories (Figure 6-2); structure, process and outcome (Donabedian, 1978). Where structure represents the material resources, human resources and organizational structure available at health facilities. Process includes the action undertaken to deliver care and comprise the HCWs determining the diagnosis and delivering treatment as well as the patient seeking care. Process is seen as having a more direct impact on outcomes than structure. Finally, outcome means the effect of care on the health of a patient. Although not easy to assess or link outcome to process, it is likely that poor processes of care leads to detrimental effects on the health of patients (Donabedian, 2002). Although it was beyond the scope of the current study to identify the outcomes of errors on patients, it was likely that, outside this study, some errors were not prevented, and patients were harmed. Figure 6-2 is an illustration of how the identified deficiencies impacted on the quality of care at the cancer centre.

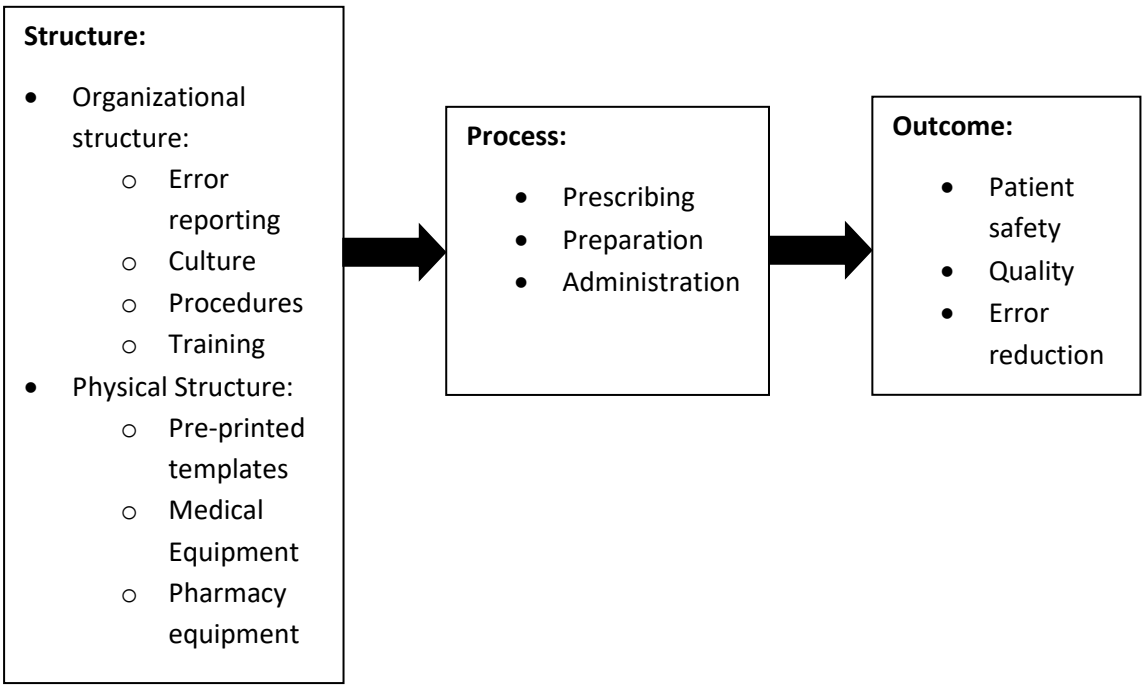


Figure 6-2 Quality of care provided at the cancer centre based on Donabedian model (adapted from Glickman et al 2007 p 342)

6.3.1 Structure

Donabedian identified that structure is the major determinant of quality of care and can hence be seen as the driving force of process (Donabedian, 2002). Glickman and colleagues argued that the attributes of structure are beyond the physical resources in an organization but includes organizational capabilities such as leadership, culture and organizational design (Glickman et al., 2007). It can hence be deduced that patient safety culture can be regarded as an integral attribute of structure.

In this study setting, structure was reported to be lacking in a number of attributes. Firstly, there were reported inadequate provision of equipment required for delivering a standard cancer service. Secondly, the HCWs received minimal training and hence lacked the expertise to work in a specialist cancer centre. Thirdly, the organizational structure was deficient in safety requirements such as the lack of clearly written procedures of work. Finally, the apparent absence of incident monitoring, learning from incidents, poor team work and the use of punitive action when dealing with errors, meant there was a lack of patient safety culture. Hence, the substantial deficiencies in structure at the cancer centre, would have a profound effect on processes involved in delivery of care.

6.3.1.1 Provision of resources

Few of the barriers to patient safety identified by staff can be overcome without the engagement of leadership from government, to provide resources and to re-enforce obligation towards staff well-being and patient safety (Aveling et al., 2015). Although, not sufficient on their own, additional resources are fundamental to achieve patient safety improvements at the cancer centre. However, the economic and political perspective of the country must be considered. Similar to its neighbours, Sudan is classified as a low-middle income country and the proportion of public spending on health is among the lowest at 6.5% (WHO, 2013b). Hence, there is a need for sourcing or re-allocating extra funding to the healthcare section. Additional funding is traditionally obtained from partnerships with high income countries, international health agencies and the global fund who usually work with countries to improve the health outcomes of their citizens. Funding from the global fund to poor countries such as Rwanda, have achieved substantial infrastructure improvements which have contributed to a reduction in mortality associated with communicable diseases such as malaria, HIV and Tuberculosis by up to 90% (Farmer et al., 2013). However, the political scenario in Sudan is a deterrent to accessing these resources. The country is controlled by a military dictatorship and has been identified, by the US government as a supporter of international terrorism and consequently sanctions were imposed in 1997, as a means to exert pressure on the government to abide by international law (Hamid, 2012). Sanctions were used in the post- cold war era as an alternative to military action but have extended in this situation beyond military embargos and currently restricts both economic trade and humanitarian aid. Consequently, the economy of the country has been adversely affected with a direct impact on health expenditure. Furthermore, pharmaceutical companies, in alliance with the US, have ceased trading with Sudan and hence cannot extend their corporate responsibility to the country. The consequent disruption in procurement of drugs and equipment necessary for provision of health has led to severe degradation of the health services including cancer care (Hamid, 2012). The politics involved in imposing sanctions have so far not succeeded in their goals, and may hence be considered ineffective and immoral, particularly when the effects touch the lives of the most vulnerable; the sick (Smith, 2004). Given the current circumstances, there is no doubt that the solution requires internal efforts. Mainly, relocation of funds is necessary to procure equipment required for patient care, improve the skills of both management and HCWs to achieve improvements in patient safety. However, attention must also be directed to improving the staff working conditions and morale. Similar countries in the region have

prioritised healthcare expenditure and increased public spending in health to 20% of Gross Domestic Product, achieving better health infrastructure (Farmer et al., 2013).

6.3.1.2 Culture

Current thinking, regarding the concept of patient safety, places the prime responsibility for adverse drug events on deficiencies in organizational factors such as flaws in system design and processes rather than individuals (Khatri et al., 2009). The current study has identified a need for a culture change, when dealing with errors. The fundamental component of this culture change is the willingness to openly discuss concerns about the delivery of care in a manner that identifies failures and leads to appropriate conclusions regarding their management (Frankel et al., 2003). In order to achieve this, two issues must be addressed, incident reporting and action towards errors. Incident reporting provides an opportunity to analyse errors, identify their causes and design strategies to eliminate or mitigate those errors. The benefits on patient safety, of incident reporting regarding medication errors associated with the use of chemotherapy can be illustrated by one example. Vincristine chemotherapy is commonly used and has been associated with a number of fatal events when administered intrathecally rather than intravenously. UK policy was changed so that vincristine should now be prepared as a minibag infusion rather than in a syringe. This simple design solution, along with improved labelling, provides an additional step to alert healthcare professionals that vincristine should only be administered via the intravenous route (Noble et al., 2010). To date, no vincristine deaths associated with intrathecal administration have been reported to the Department of Health since this policy change (Franklin et al., 2014).

The WHO recommends that incident reporting is integrated into healthcare and there is evidence that this has been addressed in Sudan (Wilson et al., 2012). However, there appear to be issues with implementation of incident reporting because this was not seen at the study hospital. The national scheme proposed by the WHO, could be augmented by a local incident reporting system at the cancer centre. An example of a simple, low cost system was described by Womer and colleagues (2002) during early safety improvements at a major cancer centre in the US. They designed an incident reporting form and asked HCWs to report errors by filling the forms and dropping them into specifically designated boxes placed around the hospital (Womer et al., 2002). The authors reported an increase in incident reporting by more than 100% over one year, which they attributed to ease of use of the system, anonymous reporting and non-punitive reporting. Findings from this early work, confirms the importance of a blame free culture in response to errors.

Most errors observed in the current study, were errors committed by well-meaning HCWs, best dealt with by focusing on improving systems rather than people (Bradley et al., 2012). However, during the course of this study, violations to best medical practice and some reckless behaviour that would inevitably result in patient harm, were observed and described by participants. For example, the nurse who neglected to dispose of syringes and sharps in designated containers, may be held accountable for their actions. Failure to comply with simple safety measures such as not sharing syringes, adhering to chemotherapy guidelines and writing prescriptions after appropriate review of laboratory data, may not be appropriately managed using the no blame approach. In most healthcare settings, finding the right balance between accountability and no blame is challenging and even more so in the current setting, where political power dictates who takes decisions, hindering the legitimacy and accountability of the organization (Bradley et al., 2012). Hence the question is not how to punish the nurse who throws sharps on the floor, but what happens when they wilfully and habitually ignore safety rules despite education, system improvements and training in clearly written procedures (Wachter et al., 2009). Therefore, the management of these situations must be just.

Implementation of a low cost intervention such as incident report monitoring has the potential to impact positively on safety culture at the cancer centre. This is supported by qualitative work conducted by Abdallah (2011) in a cardiac hospital in Sudan. The author implemented the WHO surgical safety checklist in cardiac surgery, which resulted in better teamwork, increase in HCW perception of patient safety and improved patient safety culture (Abdallah, 2011).

6.3.1.3 Specialist equipment for preparation of cytotoxics

One of the major findings of the current research was the significant error rate observed when nurses prepared and administered chemotherapy. It is of concern that without the presence of observers, all these errors would have reached patients and it is likely that these errors continue to occur. Furthermore, nurses and other hospital workers not directly involved in the preparation of these drugs were put at increased risk for harm from spills of cytotoxics. This area had been previously identified as a priority for service development by the pharmacy department, at the study hospital. Through concerted efforts and advocacy, three positive pressure isolators were procured, however, they are currently only used to prepare high dose chemotherapy for paediatrics. The use of centralised pharmacy preparation of chemotherapy has been described in the last quarter of the twentieth

century (Anderson et al., 1983) and is recommended as a risk management tool by international oncology bodies (ISOPP, 2007b). Centralisation of preparation of cytotoxics has achieved many benefits, with reduction in risk to both patients and staff (see Chapter 5). The controlled environment in pharmacies provides the appropriate conditions to prepare cytotoxics which reduces the risk of error in comparison to the clinical environment of wards (Anderson et al., 1983;Beaney, 2010). Furthermore, the use of these systems has achieved lower environmental contamination and personnel exposure in comparison with preparation on open benches (Connor et al., 2002). However, a large investment is required for the running of an appropriate clean room facility is not achievable in Sudan. In Kenya, an oncology pharmacy department has reached a compromise by installing cytotoxic cabinets in secure rooms without the recommended and costly aseptic environment (Strother et al., 2012). The authors described a multifaceted intervention that included standardisation of chemotherapy protocols using cost effective methods, bulk purchasing of drugs, training staff and safe disposal. Although, they have not published quantitative data of the impact of their intervention on patient and staff safety, they did report that immediate benefits were achieved in reduced occupational exposure to staff and patients, reduced cost and controlled waste disposal (Strother et al., 2012). Hence, a pragmatic decision must be reached by pharmacy and hospital managers, at the study hospital, to optimize the current equipment in preparation of cytotoxics.

6.3.1.4 Standardisation of prescriptions

Another target for intervention identified by the current study, and one that may be achieved at relatively low cost, is the use of pre-printed prescription templates. Although CPOE has been adopted by a significant number of cancer centres in developed countries, it is not entirely without faults (Meisenberg et al., 2014;Huertas Fernandez et al., 2006;Kim et al., 2006;Kozakiewicz, 2005;Voeffray et al., 2006). However, it has the potential to reduce errors and harm significantly. A study carried out in a cancer centre in the USA has shown that introduction of CPOE reduced prescribing errors by more than a half and serious errors likely to cause harm by one quarter (Meisenberg et al., 2014). Such interventions must be contextualised according to the capabilities of the setting (Bates et al., 2009). CPOE requires substantial capital investment (Doolan et al., 2002) which is lacking in cash strapped countries such as Sudan. A simple intervention which has a proven record of success and is low cost, is the use of pre-printed prescription templates. Pre-printed prescriptions ensure that the content of prescriptions are comprehensive and the format is consistent, legible and standardised (Ehringer et al., 2008). Their use in cytotoxic chemotherapy has shown

benefits associated with error reduction, particularly those related to omission errors (Dinning, 2005).

6.3.2 Processes

A further target for intervention, identified by participants, was the lack of work based procedures and guidelines. Furthermore, the types of errors were common and were committed by members of all teams regardless of their experience or training. It is likely that staff committed errors in many instances because they had no formal guidance on how to perform the process of care. Procedures and guidelines based on best evidence and essential for standardisation of care were not accessible at the study hospital. Consequently, staff appeared to improvise and use their own knowledge which may have been outdated. The lack of access to guidelines and procedures has been reported in another Sudanese hospital (Siddiqi et al., 2012). An assessment based on the WHO Patient Safety Friendly Hospital Initiative in a teaching hospital in Sudan, revealed that although a number of SOPs have been developed, they were not implemented and hence they were not accessible to staff (Siddiqi et al., 2012).

A simple strategy to improve the quality of the process of care is to introduce routinization which could be achieved by introduction of policies, procedures and guidelines (Donabedian, 2002). SOPs are an essential requirement for the provision of cancer care and the prescribing and administration of cytotoxic chemotherapy (ASHP, 2002;Carrington et al., 2010a) . The development of SOPs and guidelines can significantly reduce errors (Carrington et al., 2007), but they have to be accompanied by intensive training and auditing (Rowe et al., 2005). Findings from studies conducted in Sudan and other countries of low income have shown that simple dissemination of guidelines is ineffective (Salih et al., 2014). In their survey of 218 children diagnosed with pneumonia, at a children's hospital in Sudan, Salih and colleagues (2014) identified that although WHO pneumonia guidelines had been adopted by the Sudanese Paediatrics Association, a low adherence , less than 20%, was observed. However, in a neighbouring country (Kenya), a study investigating the feasibility of implementing family planning guidelines, revealed that guideline implementation was possible through multifaceted dissemination that included, face to face training, training of trainers, provision of printed materials and supervision from trained leaders from the ministry of health (Stanback et al., 2007). Improvements in process can be achieved at relatively low financial input, through the commitment and concerted efforts from the

ministry, hospital leadership and those involved in direct patient care i.e. doctors, nurses and pharmacists to undertake development, implementation and monitoring of local guidelines and procedures.

6.4 Recommendations

The findings from this research and the conclusions made, strongly support the following recommendations. These recommendations are a set of short term and long term interventions made with a view to influence hospital leadership, HCWs and policy makers, in terms of service development and the integration of patient safety systems. The UK Medical Research Council guidance for the development of complex interventions in healthcare advocates the use of theory in intervention design (Craig et al., 2008).One such theoretical framework, the Behaviour Change Wheel (BCW), has been specifically developed to inform the design of interventions in healthcare (Michie et al., 2011).It consists of three layers (Figure 6-3). At the core of the BCW is a model of behaviour known as the COM-B, and thought to inform behavioural targets for intervention. This model hypothesizes that the interaction between an individual or group's capability (C), opportunity (O) and motivation (M) influences behaviour (B)- COM-B (Michie et al., 2014). The capability of an individual or a group of people may be physical e.g. skills or psychological e.g. the knowledge or psychological skills. Opportunity, on the other hand, may be physical such as the resources or environments necessary for the behaviour or social such as the cultural norms that influence patterns of thought. Motivation maybe reflective such as self-conscious intentions or automatic such as impulses and reflexes. Surrounding this core, is a layer of nine intervention functions, most likely to achieve behavioural change or a specified intervention strategy. The outer layer consists of seven types of policy that can be used to deliver the identified intervention functions.

The BCW has been widely used to design healthcare interventions in both the western world (Sinnott et al., 2015) and in developing countries (English et al., 2009).

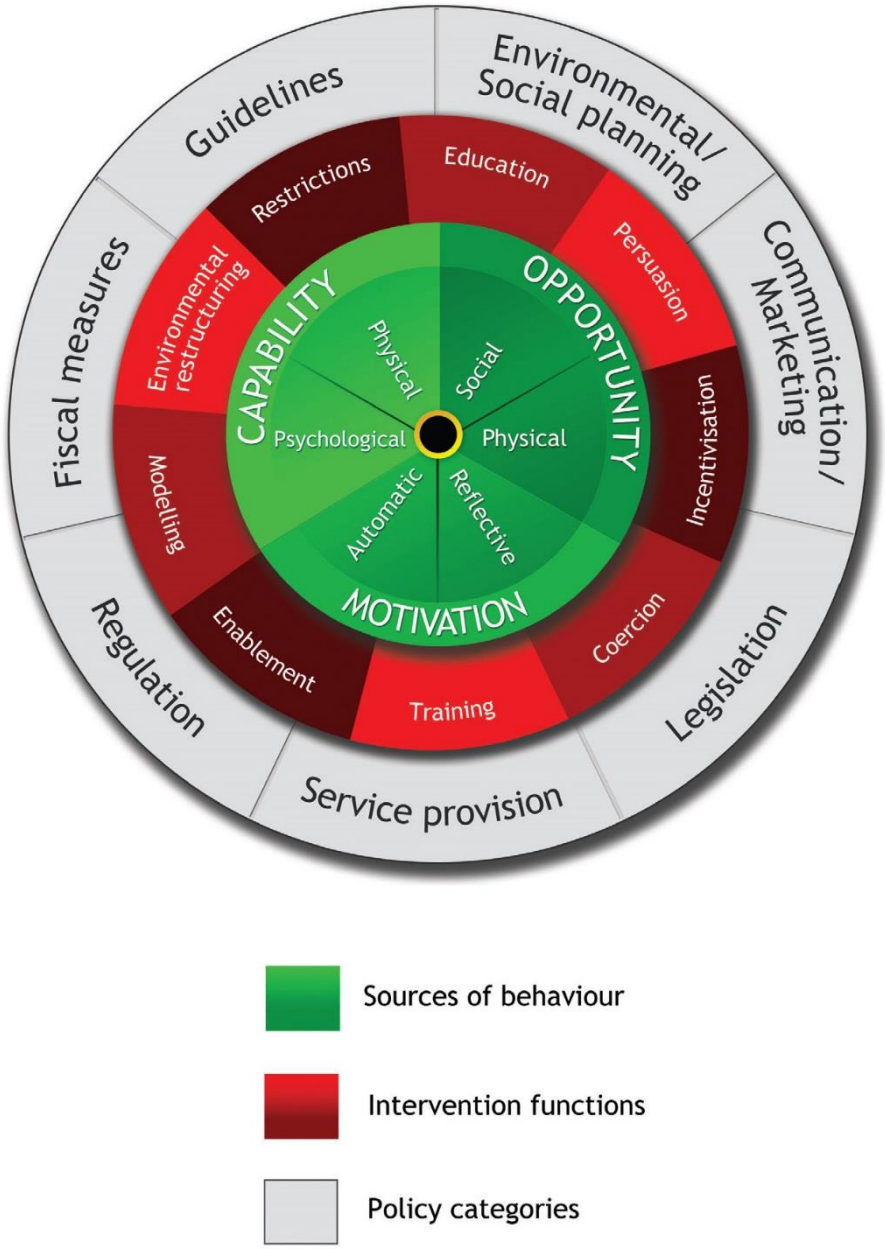


Figure 6-3- The Behaviour Change Wheel (Michie et al, 2014 p. 18)

The current thesis has identified the problems that had the potential to cause identified medication errors. Evidence from research literature reviewed within the current thesis, clearly identifies the behavioural targets (interventions) required to reduce medication errors and improve patient safety. These behavioural targets or interventions will form the basis of the recommendations and will be linked to the COM-B model.

The findings of the current work point to four interventions that are required to reduce the risks associated with cytotoxic chemotherapy. These are; centralisation of chemotherapy

preparation, standardisation of chemotherapy prescribing, incident reporting and standardisation of care. Using the COM-B model, these interventions have been inked to intervention functions and policy categories (Table 6.1).

The first intervention is based upon reducing the risk of unsafe preparation of cytotoxic chemotherapy. The findings strongly indicate that preparation of chemotherapy on the wards constitutes a safety hazard for patients, nurses and other HCWs in the cancer hospital. Therefore, on the basis of these findings, an intervention to reduce this risk is a priority which requires immediate attention. Hence, the first intervention to centralise the preparation of cytotoxics in the pharmacy department. Using the COM-B model, this intervention was coded as opportunity and capability and linked to intervention functions; environmental restructuring, enablement and training (Table 6-1). In order to avoid the prohibitive cost of building an aseptic clean room, a pragmatic approach may be adopted, which optimises the use of the currently available isolators (Physical Opportunity). The isolators are placed in a safe locked room, with uncontrolled air inflow but with a high level of cleanliness aiming for Grade D EU GMP standards (ISOPP, 2007b). It is envisaged that the process of centralisation of all intravenous cytotoxic chemotherapy preparation would require retraining and increasing the current pharmacy workforce (Physical Capability). In order to ensure the success of this intervention, short term and long term policy changes are required. Hence, the MoH are required to deliver the financial support and technical support required to set up the unit, train some of the available staff and create new jobs to provide the necessary workforce to operate the cytotoxic preparatory unit (Service Provision). In the long term, sustainability of this intervention can be assured by legislating the handling of hazardous substances within healthcare settings (Legislation) and the introduction of guidance that regulate the practice of healthcare staff dealing with cytotoxic chemotherapy (Regulation).

The second set of interventions relate to the prescribing process and are targeted at doctors responsible for prescribing cytotoxic chemotherapy. The findings from the current study, revealed a large proportion of prescribing errors with the potential to cause serious/ significant harm to patients and some with the potential to cause life-threatening harm. The prescribing process was not standardised and the majority of these errors may be eliminated if the doctor had access to a specific set of information pertinent to safe prescribing of cytotoxic chemotherapy. Hence, it is recommended that chemotherapy prescribing is standardised. Using the COM-B model, this intervention was coded to opportunity and capability and linked to intervention functions; restrictions, training and

persuasion (Table 6-1). Handwriting of chemotherapy should be restricted by means of creating a set of comprehensive standard prescription templates (Restrictions). The purpose of these templates is to standardise prescribing and provide doctors with the necessary information. For example, the prescription template would contain the pre-requisite laboratory investigations for prescribing chemotherapy, their limits and recommended dose modifications in situations where the patient has developed toxicities. Hence, doctors would be able to quickly identify laboratory values beyond the acceptable limits and modify chemotherapy doses accordingly. To enable this intervention, both the clinical and administrative leadership at the hospital are required to develop competency based training packages that provide both new and existing doctors with the necessary information required for prescribing chemotherapy (Training). Implementation of the intervention requires that doctors who are given the task of prescribing cytotoxic chemotherapy are encouraged to complete training aimed at improving their prescribing and to ensure they are competent to achieve the tasks given (Persuasion). The success of this intervention can be achieved by regulating the practice of HCWs involved in prescribing chemotherapy through the introduction of a policy that limits prescribing to competent staff (Regulation).

The third intervention is concerned with incident reporting systems at the cancer hospital and is targeted at the hospital administration, HCWs in direct contact with patients and the MoH. This research clearly identified that errors were common and repeated by all healthcare teams at all levels of experience and knowledge. The extent, nature and possible solutions to these errors are not shared with members of the healthcare team, and hence errors recur. It is therefore, recommended that in the short term, an anonymous incident reporting system is developed. Using the COM-B model, this intervention was coded to behavioural functions; capability and opportunity and linked to intervention functions; coercion, training, and incentivisation (Table 6-1). This would involve development of a simple pre-printed form available at nurse stations, doctors' offices and the pharmacy. These forms should be composed of tick boxes which would enable HCWs to complete without fear of disclosure and hence ensures anonymity (Coercion). Staff should be trained to complete a form by hand and place them in designated boxes situated in patient care areas, in the event of an error or and AE (Training). However, the presence of an incident reporting system requires an accompanied feedback mechanism to be established (Incentivisation). Healthcare teams are required to create a feedback mechanism where a nominated member of staff collects the incident reporting forms, analyses the content and

presents them at periodical meetings (monthly or quarterly), which may initially be arranged according to individual healthcare teams (nurses, doctors and pharmacists). HCWs at all levels would be encouraged to attend these meetings in order to discuss solutions to the errors. It is envisaged that implementation of this anonymous system would support development of a mature patient safety culture at the cancer hospital. In order to achieve a patient safety culture, this intervention should be scaled up to the national level, whereby future MoH policy requires the creation of an independent body that collates, analyses and reports on patient safety incidents (Guidelines).

Finally, the last intervention is related to standardisation of care, and is directed, in the short term, at the administrative and clinical leadership of the study centre and in the long term at the MoH. The findings of this study showed that there were considerable variations in the processes followed during the delivery of care at the cancer hospital. Pharmacists, nurses and doctors were unaware of the presence of SOPs at the cancer centre, a factor which may have contributed to the errors identified in the current study. Hence, a multidisciplinary team should be created to develop the SOPs required to deliver care during the chemotherapy process. Using the COM-B model, standardisation of care can be coded to psychological capability and linked to intervention function reflective motivation, enablement and modelling. In order, that SOPs are effective, they should be accompanied by a multi-modal implementation process (Grimshaw et al., 1993;Stanback et al., 2007). Hence, the SOP development team is charged with the dissemination of material required to inform staff about SOPs (Modelling). The effectiveness of SOPs and their modification relies on auditing of practice (ASHP, 2002). Hence, a multidisciplinary team responsible for auditing and regular updating of SOPs should be appointed (Enablement). In the long term, the MoH would be required to create a body which monitors the implementation of SOPs (Legislation).

Table 6-1- Linking COM-B components to intervention functions

Intervention strategy	Intervention function	Behavioural targets using COM-B	Policy categories
Centralisation of chemotherapy preparation	**Environmental restructuring**: Design an EU-GMP grade D room for preparation of cytotoxic chemotherapy	Physical opportunity	**Legislation**: Introduce legislation on the safe handling of hazardous materials **Service provision**: Provide financial resources required for design of chemotherapy preparation unit
	Enablement: Increase staff numbers	Physical capability	**Service Provision:** Create jobs for pharmacy staff
	Training: retrain pharmacists in preparation of cytotoxic chemotherapy	Physical capability	**Regulation:** Regulate the practice of staff handling and dealing with cytotoxic chemotherapy
	Enablement: Competency based programmes	Psychological capability	

Table 6 1- Linking COM-B components to intervention functions (ctd)

Intervention strategy	Intervention function	Behavioural targets using COM-B	Policy categories
Standardisation of chemotherapy prescribing	**Restrictions:** Design standard pre-printed chemotherapy templates and restrict the use of hand written prescriptions	Physical Opportunity	**Regulation:** Introduce policy which regulates prescribing of chemotherapy and limits the process to competent healthcare worker
	Training: develop competency based training packages that provide both new and existing doctors with the necessary information required for prescribing chemotherapy	Physical Capability	
	Persuasion: Encourage doctors to complete training aimed at improving their prescribing	Psychological Capability	

Table 6 1- Linking COM-B components to intervention functions (ctd)

Intervention strategy	Intervention function	Behavioural targets using COM-B	Policy categories
Incident reporting	**Coercion:** Anonymous incident reporting forms	Physical Opportunity	**Guidelines**: Create a national body to monitor patients safety incidents and share information on safety risks
	Training: Training staff in importance of incident reporting	Psychological Opportunity	
	Training: Analysis of incident reporting	Social Opportunity	
	Incentivisation: Feedback on incident reporting	Social capability	
Standardisation of care	**Reflective Motivation:** Create and audit standard operating procedures(SOPs) for practice	Psychological capability	**Legislation:** Create a body to oversee the implementation of healthcare based SOPs
	Modelling: Distribution of SOPs among HCWs		
	Enablement: Guidelines for auditing of SOPs		

6.5 Limitations to the study

This study has limitations as it was conducted in one cancer hospital in Khartoum, and the extent to which the findings are generalizable could not be tested within the scope of the current study. The study site, however, is one of two cancer centres in the country and is unlikely to be atypical in terms of structural characteristics or patient safety risks. Given the national funding problems, many of the issues relating to the procurement of equipment and staff training are likely to apply to other healthcare facilities.

The use of qualitative methods has inherent weaknesses as discussed in chapters 3, 4 and 5. However, methods used in developed countries based on patient records cannot be employed in a data poor country such as Sudan where the WHO has recommended, prospective qualitative methods as a means to study patient safety (WHO, 2010).

Another limitation to the study was the recruitment of a small number of participants in the critical incident interviews. The recruitment process was hampered by staff fears of possible retribution if they discussed errors. The study was explorative and the results were not intended to be generalisable, but a larger number of participants would have allowed deeper analysis.

Finally, members from the hospital administration and the ministry were not included in the current study. This would have allowed some of the assumptions made, following the views of HCWs in direct patient contact, to be confirmed. This was not possible at this stage, due to the oppressive nature of management at the time of the study. Furthermore, parallel research in developing countries has been based on the views of HCWs in direct contact with patients (Aveling et al., 2015).

6.6 Further work

This thesis has highlighted the risks associated with prescribing, preparation and administration of cytotoxic chemotherapy at one cancer centre and suggested recommendations and interventions to improve patient safety. The acceptability of interventions may be assessed through consultations with other stakeholders such as senior management, clinical team leaders and members from the MoH. The process of behaviour change identified in the current study can be achieved and sustained through the

aggregation of small changes. Once, the interventions are shown to be acceptable, a series of pilot work can be used to implement each intervention in a stepwise fashion. Scaling-up of each intervention would require the consideration of the local context and health policy before widespread implementation. Hence, future work could revolve around assessing the impact of such the recommended interventions on patient safety. A number of future studies can emerge from this work.

Firstly, the incident reporting scheme could be evaluated using root cause analysis to identify contributory causes to errors and provide a feedback to staff. Secondly, the implementation of SOPs may be assessed using auditing and focused interviews to assess acceptability and identify factors contributing to instances of non-adherence. Finally, the study may be repeated to investigate the impact of these interventions on patient safety culture and medication errors.

6.7 Summary

Patients receiving cytotoxic chemotherapy at a major cancer centre in Sudan were at considerable risk of being harmed due to their treatment. The risks in patient safety at the hospital are manifested in the lack of patient safety culture, the occurrence of common medication errors in both prescribing and administration of chemotherapy and the high potential clinical significance of those errors.

It is envisaged that implementation of some of the low-cost solutions outlined in the recommendations would be financially and technically feasible and would dramatically improve patient care. Behaviour change is a lengthy process but is possible through the commitment of frontline staff and those responsible for both administrative and clinical leadership. The recommendations, described in this thesis have the potential to improve patient safety culture at the study hospital and hence improve the medication error rate and reduce the safety risks for both patients and the staff preparing and administering chemotherapy.

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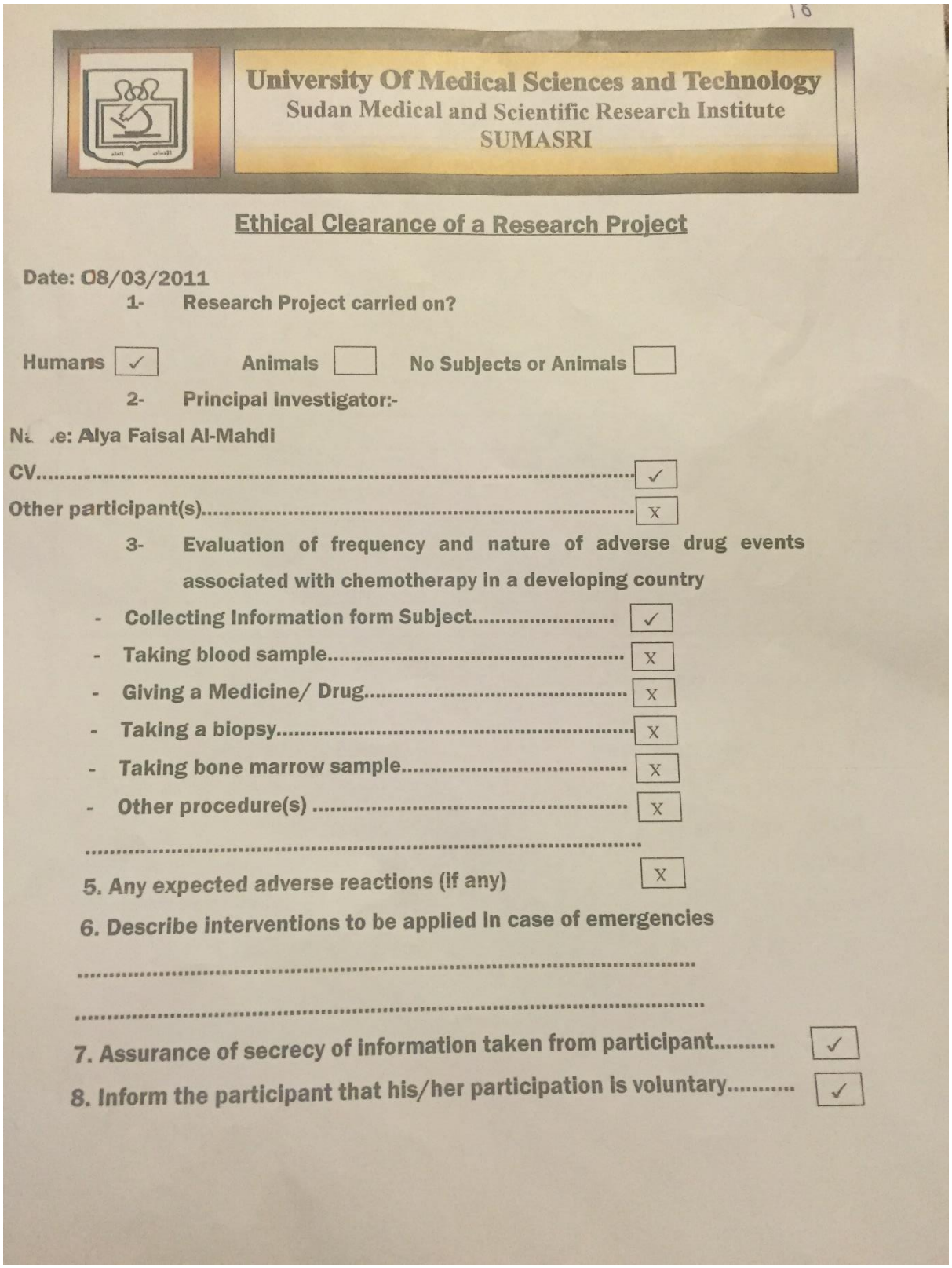
APPENDICES

Appendix 1- Approved list of chemotherapy protocols at study hospital

Chemotherapy Protocols Approved for use at RICK	
Breast Cancer Protocols:	
Anthracycline Based Therapies-	FEC- 5Fluorouracil, Epirubicin, Cyclophosphamide FAC- 5Fluorouracil, Doxorubicin, Cyclophosphamide AC- Doxorubicin, Cyclophosphamide
Taxane Based therapies-	AC-T, Paclitaxel x 4 followed by Doxorubicin, Cyclophosphamide x4 TEC- Docetaxel, Epirubicin, Cyclophosphamide, TAC- Docetaxel, Doxorubicin, Cyclophosphamide
Single Agent Therapies-	Vinorelbine, Docetaxel, Carboplatin, Paclitaxel, Gemcitabine
CMF-	Cyclophosphamide, Methotrexate, 5Fluorouracil D1 and D8
Gastrointestinal-	
Fluoropyrimidine based therapies-	De-gramont- 5fluorouracil, Folinic Acid over 48 hours, FolFox- 5 Fluorouracil, Folinic Acid over 48 hours, CapeOx- Capecitabine, oxaliplatin, GemOx- and 5Fluorouracil, mitomycin.
Gemcitabine combination	Gemcitabine, Oxaliplatin
Cisplatin Combination	Paclitaxel, Cisplatin, 5Fluorouracil ECF- Epirubicin, Cisplatin, 5Fluorouracil
Single agent	Oxaliplatin, Gemcitabine, 5 Fluorouracil
Head and Neck-	
Cisplatin combination-	Cisplatin, 5Florouracil Cisplatin, docetaxel, 5Fluorouracil Cisplatin, docetaxel
Gynaecologic Cancers	
Cisplatinum Combination-	5FU Cisplatin, Cisplatin Paclitaxel, BEP: Bleomycin, Etoposide, Cisplatin

Taxane Platinum doublet-	Paclitaxel carboplatin
Single agent-	Cisplatin, Paclitaxel
Others	Choriocarcinoma trial
Haematological Malignancies	
Lymphoma protocol	ABVD: Doxorubicin, Bleomycin, Vinblastine, Dacarbazine D1 and D15 CHOP: Cyclophosphamide, doxorubicin, vincristine, prednisolone COP: Cyclophosphamide, vincristine, prednisolone
Lung Cancer	
Platinum Doublet	carboplatin vinorelbine and carboplatin gemcitabine
Cisplatin combination	cisplatin gemcitabine, and Paclitaxel Cisplatin
Taxane doublet	Paclitaxel gemcitabine and docetaxel gemcitabine
Taxane Platinum doublet	Paclitaxel Carboplatin
Single agent	Carboplatin
Sarcoma	
Ifosfamide combination	AIM -Doxorubicin, Ifosfamide, Mesna MAID- Doxorubicin, Ifosfamide, mesna and Dacarbazine
Cisplatin combination	Doxorubicin and cisplatin
Single Agent	Gemcitabine
Urological Cancers -	
Single agent-	Docetaxel and prednisolone
Cisplatin combination	Bleomycin Etoposide Cisplatin

Appendix 2- Ethical Clearance



University Of Medical Sciences and Technology
Sudan Medical and Scientific Research Institute
SUMASRI

Ethical Clearance of a Research Project

Date: 08/03/2011

1- Research Project carried on?

Humans [✓] Animals [ ] No Subjects or Animals [ ]

2- Principal Investigator:-

Name: Alya Faisal Al-Mahdi

CV..... [✓]

Other participant(s)..... [X]

3- Evaluation of frequency and nature of adverse drug events associated with chemotherapy in a developing country

- Collecting Information form Subject..... [✓]
- Taking blood sample..... [X]
- Giving a Medicine/ Drug..... [X]
- Taking a biopsy..... [X]
- Taking bone marrow sample..... [X]
- Other procedure(s) ..... [X]

.....

5. Any expected adverse reactions (if any) [X]

6. Describe interventions to be applied in case of emergencies

.....

.....

7. Assurance of secrecy of information taken from participant..... [✓]

8. Inform the participant that his/her participation is voluntary..... [✓]

9. Inform the participant that he/she has the right to withdraw from ✓
The study .....

10. Participant consent form..... ✓

11. Proposal Details

Character	Place of Research	Duration of Research	Introduction	Objectives General	Objectives Specific
Present	✓	✓	✓	✓	✓
Absent					

Character	Type of Study	Variables	Data Collection Technique	Sample Procedure	***
Present	✓	✓	✓	✓	
Absent					

Ethical Committee decision:

Passed ✓

Prof. M.El Bagir K. Ahmed

Chairman

Ethical Committee

UMST

Signature .....

Date 21-03-2011

Not passed ☐

Prof. Abdalla .O.Elkhawed

Convener

Ethical Committee

UMST

Signature.....

Date 21/3/2011

Appendix 3.1 ARABIC TRANSLATION OF MAPSAF- DRAFT

An exploratory study into patient safety Culture-Manchester Patient Safety Framework

1- الالتزام الشامل للتقدم المستمر

A- لا توجد أى مداخلات مستثمرة فى التعرف على المشاكل فى مجالات الممارسة المثلى.
ان وجدت اى مراجعة ينقصها الهيكلة وليس هناك استجابة .

اذا وجدت بروتوكولات أو أى انظمة فهى تخدم مصلحة المؤسسة فقط ولا يوجد تحديث لهذه البروتوكولات والسياسات.

يتم تجاهل الرعاية النوعية الضعيفة وهذا المفهوم يطلق على مستوى الادارة وفرق الرعاية الصحية فى الهيئة.

B- يطور الاطار العام للتقدم المستمر استجابة لتوجيهات محددة أو من خلال الزيارات التفتيشية . تحدث المراجعة فقط استجابة لحادثة محددة وبتوجيهات من السلطات الوطنية ولا تعكس الاحتياجات المحلية. وهناك محاولات غير واقعية تتم استجابة لنتائج أي مراجعة.
يوجد الحد الادنى من البروتوكولات والسياسات وجميعها قديمة وغير مستخدمة ولا يتم مراجعة هذه السياسات الا استجابة لحادثة معينة.

تطوير بروتوكولات وسياسات جديدة يحدث استجابة لحادثة معينة أو ردا على شكاوى واردة.

C- العاملين فى الخطوط الامامية ليس لهم دور فى عملية التقدم وهم ينظرون اليها كنشاط ادارى يقاد من خلال خطوط خارجية.

يحدث الكثير من عمليات المراجعة ولكن ينقصها ربط الاستراتيجية العامة مع الاحتياجات المحلية والتنظيمية. يتحمل العاملون عبئا كبيرا مع البروتوكولات والانظمة والتى تراجع وتحدث بانتظام، ولكن نادرا ماتنفذ.

يجوز للمرضى والجمهور بالمشاركة فى مواضيع الجودة ولكن تلك خدمة ظاهرة أكثر من كونها مشاركة حقيقية.

D- هنالك رغبة وحماس حقيقين فى جميع انحاء المؤسسه من أجل التقدم المتواصل. كما هو معروف بأن التقدم المتواصل هو مسئولية الجميع وبأن المنظمة بكاملها والتى تشمل المرضى والعامة معنيين بهذه المسئولية.

تهدف هذه الهيئات أن تكون مراكزمتميزة يتم مقارنة ادائها مع المراكز الاخرى.

تضمين الاطباء الممارسين وملكيتهم لعملية المراجعة يؤدى الى التقدم المتواصل. تطوير البروتوكولات والسياسات ومراجعتها تتم من قبل العاملين ويتم استخدامها كاساس فى الرعاية والخدمات. يشارك المرضى والجمهور فى اتخاذ القرارات الداخلية- وهذا مما يجعلها مراكز خدمية تركز على المرضى.

E- غرس ثقافة التقدم المتواصل داخل المؤسسه وهو اساس اتخاذ القرار على كل المستويات.

وتعتبر المؤسسة مركز للاداء المتميز نتيجة للتقييم المتواصل للاداء مقارنة بمثيلاتها داخل وخارج الخدمة الصحية. تقوم الفرق بتصميم اجراء المراجعة بالتركيز على الناتج وبالتعون مع المرضى والجمهور.

يكون العاملون فى يقظة تامة لاحتمال وجود مخاطر على السلامة.وهذا يعنى تقليص الحوجة للبروتوكولات والانظمة مع مرور الزمن عندها تصبح الممارسة المبنية على البرهان هى عامل طبيعى اضافة الى أن سلامة المريض تكون دائما ذات اولوية فى أذهان الجميع. وعلى هذا يكون المرضى والجمهور يتم تضمينهم بطريقة ذات معنى وروتينية فى المشاركة الداعمة والتغذية الراجحة.

2- **الاولوية للسلامة**

A-تعطى اولوية بسيطة للسلامة

هناك بعض انظمة ادارة المخاطر مثل الاستراتيجيات واللجان ولكن بدون مردود حقيقى. المؤسسة لا تعطى المخاطر الخاصة لها حيث يعتقدون أنه فى حالة وقوع أى حادثة تهدد سلامة المريض فان شركات التأمين سوف تكفلهم.

B- تصبح السلامة ذات أولوية فقط عند وقوع حادث ولكن فى بقية الوقت تكون الخدمة مجرد حديث فى الموضوع عدا اللايفاء بالمتطلبات القانونية

هناك اثبات ضعيف فى تنفيذ استراتيجية ادارة المخاطر .تناقش السلامة فى مجلس المؤسسة بعلاقتها بوقوع حادثة معينة كل الاجراءات هدفها الحماية الذاتية وليس حماية المريض.

C- السلامة لها أولوية مرضية وهنالك انظمة عديدة (وتشمل تلك التى تتكامل مع منظور المريض) فى مكان الحماية.لكن هذه الانظمة ليست معممة على العاملين ولا تراجع. وتفتقر المرونة فى الاستجابة للاحداث غير المرئية وتفشل فى التفاعل مع الامور المعقدة.
مسئولية ادارة المخاطر تستثمر فى شخص فردى لا يضمنها فى الهيئة الواسعة. مما يجعلها ثقافة مفروضة

D- ترتقى السلامة داخل الهيئة ويكون العاملين فيها نشيطين فى الاشتراك فى أمور السلامة وعملياتها. المرضى والجمهور والهيئات الاخرى يشاركون فى ادارة المخاطر ومراجعتها. التدابير المتخذة تهدف لحماية المرضى ولا تهدف للحماية الذاتية.يتم تحديد المخاطر على نحو استباقى باستخدام تقييم المخاطر المنظورة واتخاذ الاجراءت اللازمة لاداراتها.هنالك حدود واضحة للمسائلة وحتى حين يأخذ أحد الافراد الريادة فى فى سلامة المرضى فى المؤسسة، وهذا هو الجزء الاساسى فى دور كل الاداريين.

E- السلامة لها الاولويه القصوى فى المؤسسة وينظر لمسؤلية السلامة كجزء من دور كل الافراد ويشمل ذلك المرضى والجمهور. يقيم العاملون المخاطر وينظرون للتقدمات الممكنة.سلامة المريض من الامور الساخنة
فى كل المؤسسة وتغرس فى ممارسات كل العاملين ابتداءا من مجلس الادرة والمدراء الى فرق الرعاية الصحية الذين لديهم احتكاك يومى مع المرضى، وذلك يشمل موظفى الدعم واشتراك المريض فى امور سلامة المريض ومراجعته لها مؤسس بطريقة مثلى.

3- أخطاء النظام والمسئوليات الفردية

A- يتم النظر الى الحوادث بأنها سوء حظ وخارجة عن سيطرة المؤسسة، وتحدث نتيجة لاخطاء العاملين أو سلوك المرضى. توجد ثقافة لوم قوية فى المؤسسة ويعرض الافراد لاجراءات توبيخية ولوم.

B- تنظر المؤسسة الى نفسها كضحية للظرف. وينظر للافراد كسبب ويكمن الحل فى اعادة التدريب والاجراءت الجزئية. عند وقوع الحادثة ليست هناك محاولة لدعم الجهات المعنية بما فى ذلك المرضى وأقاربهم.

C- هناك اعتراف بأن الانظمة تساهم فى الاحداث وليس الافراد فقط.وتقول الؤسسة بأن لها ثقافة الانفتاح العادل ولكن العاملين لا يشعرون بهذا.بروتكولات الانفتاح والانغلاق كتبت للتأكد من أن العاملون والمرضى وراعو المرضى يحصلون على الدعم عند الحوادث ولكنهم غير ملمين بالمعرفة عنها ولا باستخدامها.

D- من المقبول أن الحوادث هى عبارة عن مزيج من أخطاء الافراد والانظمة. الؤسسة لها سياسة انفتاح تعاونية. ويتبع حادثة تهدد سلامة المريض، تحليل للانظمة لاتخاذ القرار بشأن عوامل الانظمةوالافراد والتى لها علاقة تساهمية مثل .....شجرة قرار الحدث.وهذه العملية تخدم اتخاذ القرارات. عند توقيف العاملين وهناك نهج عادل وثابت فى التعامل مع أمور الموظفين بعد وقوع الحوادث. الؤسسة صريحة ومنفتحة مع المرضى ومقدم رعاية المرضى عند وقوع حادثة الحاق أذى أدت الى الحاق أذى جسيم أو موت، ولكنها لا تناقش كل انواع الحوادث.

E- يتم ملاحظة فشل النظام ويكون الموظفين على دراية تامة بمسؤلياتهم الشخصيةفيما يتعلق بالاخطاء والتبليغ بذلك. تمكن الانظمة المتكاملة فى تحليل الحوادث التى تهدد سلامة المريض والشكاوى والدعاوى القضائية
العاملون والمرضى وأقربهم يتعاونون بنشاط ولهم دعم من بداية الحادثة. المؤسسة لها مستوى عالى من الانفتاح

والثقة. المؤسسة أيضا منفتحة ومخلصة مع المرضى ومقدمى الرعاية نحو جميع أنواع حوادث المرضى بغض النظر عن مستوى الضرر الواقع.

4- تدوين الحوادث وأفضل السبل لذلك

A- توجد أنظمة مخصصة للتبليغ عن الحوادث ولكن الؤسسة فى حالة جهل تام الا فى حالة وقوع حادثة خطرة أو استلام رسائل من المحامين.
تسود المؤسسة ثقافة اللوم العالية حيث يتعرض الافراد للاجراءات التأديبية ويصبحون ضحية للنظام.

B- هنالك نظام تبليغ للحوادث غير ناضج، ولكن الموظفين لا يشجعون للتبليغ عن الحوادث. تجمع معلومات دقيقة ولكن لا يتم تحليلها.
هناك ثقافة لوم وعليه يكون الموظفين مترددين فى التبليغ عن الحوادث. عندما تقع الحوادث، ليست هناك محاولة لدعم الذين يشملهم الحادثة.

C- يوجد نظام مركزى للتبليغ عن الحوادث من غير الحاجة الى معرفة المبلغ ويركز على تعبئة الاستمارات. هناك محاولات بغرض تشجيع الموظفين والمرضى للتبليغ عن الحوادث (ويشمل ذلك الحوادث التى منعت أو التى منعت أو التى لم تؤدى الى أى أضرار) على الرغم من ذلك فان الموظفين لا يشعرون بالامان والمرضضى لا يشعرون بالارتياح عند التبليغ عن هذه الحوادث. تعتمد المؤسسة مصادر أخرى لمعلومات السلامة جنبا الى جنب مع تقارير الحوادث (مثل المراجعات والشكوى).

D- التبليغ عن حوادث سلامة المريض على كل المستويين المحلى والوطنى (مثال نظام القومى لتقديم التقارير والتعليم) وينظر له كفرص تعليمية.
يوجد أساليب تبليغ ودية للموظفين والمرضى سهلة، وتسمح اختيار الاتجاهات المختلفة.

الموظفون يشعرون بالاطمئنان عند تبليغ كل الحوادث التى تهدد سلامة المرضى ويشمل الحوادث التى يمكن . تجنبها. الموظفون والمرضى ومقدمى الرعاية مدعمون منذ لحظة التبليغ.

E- التبليغ عن حوادث سلامة المريض عند الموظفين أمر طبيعى(ويشمل ذلك الحوادث التى لم تؤدى الى أضرار أو التى منعت) وللموظفين ثقة فى عمليةالاستقصاء ويتفهموا قيمة التبليغ لكل من الانظمة المحلية والقومية(مثال النظام القومى لتقويم التقارير والتعليم).
يشجع المرضى بالتبليغ عن الحوادث. وهى مؤسسة تعليمية وفيها أنظمة متينة لتدوين الممارسة المثلى ومكملاتها.

5- تقييم الحوادث والممارسة الجيدة

A- توضع الحوادث والشكوى تحت البساط ما أمكن. ويتم التحقيق فى الحوادث بطريقة سطحية بواسطة صغار المدراء بهدف قفل الموضوع و تجمع معلومات التحقيق وتخزن ويؤخذ اجراء بسيط عدا الاجراء الاداري (المحاكمة على الملأ) ومحاولات التصدى للاعلام . فى هذه المؤسسة هناك اعتراف ضئيل بسلامة الممارسات الجيدة.

B- توجه التحقيقات بهدف الحد من الاضرار فى المؤسسة وتوزيع اللوم على الافراد. التحقيقات سطحية وتركز على حالة معينة وأفعال فردية.
تقترح الحلول السريعة والتى تتعامل مع حادثة معينة ولكنها لا تحتمل أن توجه اذا زالت حدة الحادثة. وبعض التحقيقات تظل غير مكتملة.

C- كبار المدراء يشاركون فى التحقيق والذى يكون فى نطاق ضيق ويتم التركيز فيه على الافراد والانظمة.
المحيطة بالحادث. هناك اجراء مفصل لعملية التحقيق، والتى تشمل تعبئة استمارات عديدة ولا يجري التحقيق الى حد ما لفحص جذور المشكلة ودعم من يشمله الحادث ولكن كاجراء اداري ولاسترضاء المرضى ومقدمى الرعاية.

الموظفون يحفزوا لمراجعة الاجراءات وكيفية تنفيذها ولكن عملية التعليم متضاربة.

D- المؤسسة مفتوحة للاستفسارات وترحب بالمشاركة الخارجية للتحقيقات من أجل تحقيق نظرة مستقلة. الموظفون المطورتين فى الحوادث يتم شملهم فى التحقيق لتحديد جذور المشكلة والقضايا التى فى الواجهة.
الهدف من التحقيقات هو الاستفادة والتعلم من الحوادث ونشر النتائج على نطاق واسع.

تستخدم البيانات منةتقرير الحوادث فى تحليل الظواهر، تحديد النقاط الساخنة ودراسة الاثار المترتبة على التدريب. وهى مؤسسة منفتحة ذات نظرة مستقبلية.

المرضى يشاركون فى عملية التحقيق ورؤيتهم وتجربتهم وتوصياتهم مطلوبة.

E- تجرى المؤسسة تحقيقات مستقلة للحادث على الصعيدين الداخلى والخارجى وتشمل الموظفين والمرضى المعنيين. وينظر الى التحقيقات فى الحوادث كفرص للتعلم وتركز على التقدم وتشمل توصيات المرضى . تراجع عملية تحليل الحادث بطريقة منهجية ويتم مراجعتها بانتظام بعد التشاور مع الموظفين.
التعلم من الممارسة الجيدة مشتركة فى جميع انحاء المنظمة وعلى المستوى القومى. هى مؤسسة تعلم كما يتضح من الالتزام للتعلم من الحوادث فى جميع المستويات من المجلس وكبار المدراء ومن خلال فرق الرعاية الصحية وموظفى الدعم.

6- التعلم واحداث التغير

A- لا تبذل محاولات للتعلم من الحوادث عدا تلك التى تفرضها جهات خارجية مثل المساءلات الحكومية.
الهدف بعد الحادثة هو تغطية التقصير وحماية المؤسسة. وتعتبر المؤسسة أنها قد نجحت عندما تصبح وسائل الاعلام عديمة المعرفة بالحادث. لا يتم أى تعديلات عقب الحادثة بغض النظر عن تلك الموجهة الى الافراد المعنيين.

B- يوجد التعليم التنظيمى ولو قليلا وما يحدث يكون ذو علاقة لدرجة الاضطراب الذى تضرر منه كبار الموظفين. وجميع التعليم مخصص كحادثة معينة.
وكل التغييرات المبادرة عقب حدوث الحادث ليست دائمة بل هى ردود فعل للاخطاء الفردية الملاحظة ويتم وضعها وفرضها من كبار الموظفين. وبالتالى فان الحوادث المماثلة من المتوقع تكرارها.

C- هناك بعض النظم لتسهيل التعلم المؤسسى وهذه قد تشمل وضع وجهة نظر المريض فى الاعتبار الدروس المستفادة لا تعمم على المؤسسة. وتحاك بعض التغييرات القصرية ولكنها متصلة مباشرة بحادثة معينة.
اللجان والمدراء يتخذون القرارات تجاه استحداث التغييرات ولكن عدم تضمين الموظفين يؤدى لعدم دمج هذه القرارت فى أنماط العمل.

يتم شمل المرضى حتى تثبت المؤسسة للمنظمين أن لديها بعض الالتزام نحو مشاركة المريض والجمهور.

D- للمؤسسة ثقافة تعليمية ولديها عمليات لتشارك فى التعلم مثل التفكير ومشاركة تصور المريض.
هناك دعم من مجلس الادارة لتغعيل التحقيقات العميقة والدفع لتغيرات تعالج الاسباب الكامنة للحوادث. يشارك الموظفون بنشاط فى العملية وهنالك التزام حقيقى نحو التغيير الدائم فى جميع أنحاء المؤسسة.

المؤسسة تبعث فى الافق عن الفرص التعليمية وهى حريصة على التعلم من تجارب الاخرين. التعلم التنظيمى عقب الخوادث يستخدم فى التخطيط للمستقبل. وهى مؤسسة منفتحة ولها ثقة بنفسها.

E- هى مؤسسة تعليمية. وتتعلم المؤسسة من المعلومات والخبرات الداخلية والخارجية وهى ملتزمة لاشراك من هو خارج وداخل المؤسسة فى هذا التعلم.
تتم مناقشة الحوادث التى تهدد سلامة المريض (وهذا يشمل تلك التى منعت) فى محافل مفتوحة حيث يتم تمكين الموظفين فى المشاركة. يتم تقدير التعليم التنظيمى والفردى على حد السواء.

يحدث التقدم فى الممارسة من دون التأثر بحادث حيث أن الثقافة هى من نوع التقدم المستمر. ويلعب المرضى دورا اساسيا فى التعلم ويساهمون فى عمليات التغيير اللاحقة.

7- التواصل فى مواضيع السلامة

A- لتواصل بصفة عامة ضعيف ويبدأ من الأعلى الى الاسفل والموظفين غير قادرين على التحدث الى مدرائهم حول المخاطر ويتم الاحتفاظ بالاحداث داخليا ولا يتحدث عنها.

المؤسسة منغلقة فى الاساس وهنالك تواصل سلبى يرتكز على اللوم ويعطى المرضى المعلومات المطلوبة قانونيا فقط ويعد بذل جهد كبير حتى يتاح لهم الوصول اليها.

B- التواصل عامة توجيهى ويأتى باصدار تعليمات من المدراء والموظفين قادرين فقط فى الحديث الى من يرئسوهم بعد حدوث خطأ ما. التواصل غير مخصص ويقتصر على الذين يشملهم حادث معين ويعطى المريض المعلومات التى تشعر المؤسسة بأنها مناسبة فى اتجاه تواصل أحادى.

C- هنالك استراتيجية للتواصل كما توجد سياسات واجراءات تحفظ الكثير من السجلات. هناك الكثير من المعلومات التى يتم جمعها من الموظفين والمرضى والمؤسسات الاخرى ولكنها ليست مستخدمة بشكل فعال وهذا يؤدى لتكدس المعلومات مما يعنى أن مأنجز فى الواقع قليل بالمقرنة مع المعلومات الواردة من الموظفين. ويوجد نظام للتواصل بشأن المخاطر ولكن لا يتحقق أحد من أنه يعمل.

D- يخضع نظام الاتصال والسجلات للمراجعة بشكل دائم. ويوجد اتصال عبر المؤسسات لتسيير وضع المقاييس بطريقة ذات معنى.

الموظفون من كل المستويات يشاركون وتتاح لهم اليات التغذية الراجعة للمؤسسة.

تتم المشاركة بالمعلومات وهناك محاضرات تقدم بانتظام يشجع فيها الموظفين بتحديد جدول الاعمال. يتم اتصال فعال مع المرضى والجمعيات بخصوص أمور السلامة.

F- يشارك الجميع فى نقل أمور السلامة ويتعلمون من تجارب الاخرين (الجيدة والسيئة). هى مؤسسة ذات شفافية وتشمل مشاركة المرضى فى تطوير سيلسة ادارة المخاطر.
يتم تشجيع الافكار المبتكرة ويتم تمكين الموظفين لتنفيذها.

هى مؤسسة تنقل الممارسة الجيدة للداخل والخارج.

8- ادارة شئون العاملين وأمور السلامة

A- ينظر الى العاملين كأجساد ولملئ الوظائف فقط.

وعمليات اختيار الموظفين وتوظيفهم عملية بدائية. الاستخدام اللغوى سلبى وينظر الى التدنى الصحى وسجلات الحضور كأداة تأديبية.

يشعر الموظفين بأنهم غير مدعومين ويروا شئون العاملين (كالاخر) وليس (كنحن). هناك سياسة موظفين بدائية وليس هناك برامج تنمية موارد بشرية ولا توجد هناك اى صلات مع الصحة المهنية.

B- يتغير الوصف الوظيفى ومستويات التوظيف استجابة للمشاكل فقط، وعليه يكون هنالك اختيار جيد وسياسات

استبقاء فى الاماكن التى تعرضت فى الماضى للمشاكل.

بيئة العمل مفعمة باللوم والعتاب. ودعم الموظفين متاح ولكنه ضئيل ورمزى. توجد سياسة للموارد البشرية متواضعة ولكنها غير مرنة وطورت استجابة للمشاكل السابقة.

C- توجد اجراءات توظيف واستبقاء ودائما يتم مراجعة المؤهلات. واللغة المستخدمة فى ادارة الموظفين بصفة

عامة رسمية ومحايدة وتحكمها السياسات والاجراءات.

اليات دعم الموظفين يحكمها الكثير من البروقراطية وخطط العمل. هنالك اجراءات تقييم وتنمية الموظفين والصحة المهنية ولكن يتم تطبيق ذلك بطريقة صارمة وعليه لا تحقق دائما ما صممت لأجله. ينظر الى هذه الاجراءات من قبل الادارة كأداة للسيطرة على الموظفين.

D- يوجد التزام نحو مجانسة الافراد للوظائف. وهناك محاولات لفهم لماذا يحدث سوء الاداء ويوجد هناك نظام دعم مرن وواضح، تم تفصيله وفقا لاحتياجات الفرد.

تراجع عمليات ادارة شئون الموظفين عند الضرر كما يتم اجراء التغيرات اللازمة. هنالك اهتمام حقيقى حول صحة الموظفين ونظام التقييم والمراقبة والمراجعة.

يتم السعى بنشاط نحو مساهمة المرضى ومقدمى الرعاية بشأن التوظيف.

F- يستخدم اطار المعرفة والمهارت لتصميم مواصفات الوظيفة ولتمييز الكفاءات. التفكير الملئ والمراجعة (سواء كانت ايجابية أو سلبية) تحدث بطريقة مستمرة وتلقائية.
المؤسسة لها التزام نحو موظفيها، والجميع لديه الثقة فى اجراءات شئون العاملين والتى تشمل الارشاد والاشراف.

المرضى والجمهور لهم مشاركة ذات معنى فى وضع وتنفيذ أى سياسات تتعلق بالسلامة وقضايا التوظيف. شئون العاملين ليست كيانا مستقلا ولكنها جزءا مكملا للمؤسسة.

تستخدم أنظمة التحليل اثر وقوع الحادثة التى تهدد سلامة المريض عند اتخاذ القرارات نحو المساهمة النسبية لعوامل الانظمة. دور الفرد الموظف فى الرعاية الصحية. هذه العملية تخدم القرارات بشأن توقيف الموظفين وعلى هذا النحو يكون هناك نهج ثابت وعادل للتعامل مع قضايا الموظفين بعد وقوع الحادث.

9-تعليم وتدريب الموظفين

A- التدريب له أولوية ضعيفة. ويقدم فقط التدريب الذى تطلبه الحكومة.
تنظر الادارة الى تعليم الموظفين كبرنامج مزعج ومكلف ومضيعة للوقت. وبالتالى لا يوجد هنالك ضبط بشأن النوعية أو صلة للتدريب والتعليم المتلقى فيما يتعلق بالتطوير المهنى للموظفين. ينظر الى الموظفين باعتبار أنهم مدربين للقيام بعملهم وعليه لماذا يحتاجون لمزيد من التدريب.

B- يحدث التريب حيث هنالك مشاكل معينة ولها علاقة بشكل كامل على المناطق ذات المخاطر العالية حيث يتم ملئ الثغرات. هى مسئولية الفرد أن يقرأ ويتصرف ويقوم بتمويل احتياجاته التعليمية.
يرتكز التعليم والتدريب على زيادة الدخل وحماية ظهر المؤسسة بدلا من التطوير المهنى للموظفين. ليس هناك ميزانية مخصصة للتدريب ويحدث تقييم الموظفين بصورة.....

C- يعكس برنامج التدريب الاحتياجات التنظيمية وعليه يدعم التدريب فقط اذا كان يفيد المؤسسة. ولا يوجد تفكير جاد فى اشراك المرضى فى التدريب.
توجد خطط تنموية شخصية متواضعة بحيث يكون لكل شخص ملفه الخاص. ولكن هذا ليس ذو فعالية ومصدره غير مناسب ولا يعطى أولوية.

معروض عدد كبير من الدورات ولكن ليست كلها ذات علاقة بالتطوير الوظيفى ولا يتوقع أن يستفيد منها الموظفين. ينظر الى التدريب كوسيلة لمنع وقوع الاخطاء وتقييم الموظفين يرتكز حول هذا الامر.

D- هنالك محاولات لتحديد احتياجات التدريب للمؤسسة و احتياجات الافراد و تناغمها. يتم التخطيط للفرص التعليمية جيدا وتسخر لها الموارد وهى متاحة من والى كل الوكالات ذات الصلة.
وينظر للتعليم والتدريب كأساس للتطوير الوظيفى للفرد ويرتبط مباشرة بالنظم التنظيمية الاخرى مثل التبليغ عن الحادث.

يركز التقييم الوظيفى على الموظفين ويتم بنائه على احتياجات الفرد.

المحاولات أولية لاشراك المرضى والجمهور فى تدريب الموظفين جارية وبدأت المؤسسة فى فهم الدروس من تجاربهم.

E- الافراد يتم تمكينهم وحثهم للقيلم أو تولى أمر تحليل احتياجاتهم ومناقشة برامجهم التدريبية. يحدث التعلم بشكل يومى ولا يقتصر فقط على البيئة الصفية.
ينظر الى التعلم كأساس للثقافة التنظيمية. النهج المتبع فى التدريب والتعليم مرن وينظر اليه كأسلوب لدعم الموظفين حتى يدركوا امكانياتهم. يبدأ التقييم ويتم ادارته بواسطة الموظفين.

يشارك المرضى فى تدريب الموظفين للمساعدة فى فهم تصور المريض عن المخاطر والسلامة.

10- العمل كفرق

A- يعمل الافراد فى الغالب فى عزلة ولكن حينما يكون هنالك فرق فان أفرادها يكونوا أحادي التخصصات مع الاختلال الوظيفى.

يوجد توتر بين أعضاء الفريق وهناك بناء وظيفى صارم مبنى على الرتب. هى أشبه ماتكون مجموعة مجموعة من الناس جمعوا تحت توجيه زعيم اسمى.المعلومات لا يتم تبادلها بين أعضاء الفريق. يعمل الفريق بسرية.

B- يعمل الناس فقط كفريق اثر الحدث السلبى واستجابة للمطالب الخارجية. والافراد حقيقة غير ملزمين بالفريق.

هنالك تسلسل وظيفى مبنى على الرتب فى كل فريق، مطابق للتسلسل الوظيفى للمنظمة ككل. هناك فرق متعددة التخصصات ولكن أملى عليهم بأن يعملوا معا، والخدمة المثالية لفريق العمل مجرد حديث فقط. تتوالى العلومات الى أعضلء الفريق عقب كل حادثة. تعمل الفرق بطريقة دفاعية والاعضاء الجدد غير مرحب بهم.

C- وضعت الفرق متعددة التخصصات مع بعض الاستجابة للسياسات الحكومية. ولكن لا توجد وسيلة لقياس مدى فعاليتها.

ينظر الى العمل كفرق من قبل الصفوف الدنيا للموظفين كحديث فقط مبنى على فكرة التمكين.

تعطى الفرق كميات من المعلومات المدونة حول الكيفية التى يجب العمل بها. توجد اليات رسمية للمشاركة فى الافكار والمعلومات داخل وعبر الفرق ولكنها لا تستخدم بطريقة فاعلة.

فرق العمل تعمل وراء الكواليس ولا تتعدى المؤسسة الواحدة.

D- هناك فرق متعددة التخصصات وتسخر الموارد والوقت لتنمية عمليات الفرق.

بنية الفريق سلسة حيث يتناول الناس الادوار بالطريقة المناسبة لهم فى ذات الوقت. يوجد تقييم عن فعالية الفريق وتجري التغييرات عند الحاجة. الفرق متعاونة وقابلة للتأقلم.

الفرق منفتحة ومن المحتمل اشراك أعضاء من خارج المؤسسة.

F- يقدم تدريب دوري ومقيم فى ادارة موارد الفرق للفرق متعددة التخصصات المتكاملة. عضوية الفريق مرنة وبنيتها أفقية. مختلف الناس يؤدون مساهمات قيمة عند الحاجة.
الفرق مبني على التفاهم والرؤية المشتركة بدل من القرب الجغرافى.

العمل كفريق هو الوسيلة المقبولة فى المؤسسة.

الفرق منفتحة محليا ويشلرك فيها الاعضاء من مختلف المؤسسات المحلية والوطنية والعالمية.

Appendix 3.2 FINAL ARABIC TRANSLATION OF PATIENT SAFETY CULTURE TOOL ADAPTED FROM MAPSAF

An exploratory study into patient safety Culture-Manchester Patient Safety Framework - Arabic

1- الالتزام الشامل للتقدم المستمر

A- لا توجد طرق للتعرف على المشاكل فى مجالات العمل .
ان وجدت اى مراجعة ينقصها الهيكلة وليس هناك استجابة من المسؤلين .
اذا وجدت بروتوكولات أو أى انظمة فهى تخدم مصلحة المؤسسة فقط ولا يوجد تحديث لهذه البروتوكولات والسياسات.
يتم تجاهل الرعاية الضعيفة وهذا على مستوى الادارة وفرق الرعاية الصحية فى الهيئة.

B- يطور العمل لاوامر محددة. تحدث المراجعة فقط استجابة لحادثة محددة وبتوجيهات من السلطات الوطنية ولا تعكس الاحتياجات المحلية. وهناك محاولات غير واقعية تتم استجابة لنتائج أي مراجعة.
يوجد الحد الادنى من البروتوكولات والسياسات وجميعها قديمة وغير مستخدمة ولا يتم مراجعة هذه السياسات الا استجابة لحادثة معينة.

C- العاملين فى الخطوط الامامية ليس لهم دور فى عملية التقدم وهم ينظرون اليها كعمل ادارى يقاد من الخارج.
يحدث الكثير من عمليات المراجعة ولكن ينقصها ربط الاستراتيجية العامة مع الاحتياجات المحلية والتنظيمية. يتحمل العاملون عبئا كبيرا مع البروتوكولات والانظمة والتى تراجع وتحدث بانتظام، ولكن نادرا ماتنفذ.
يجوز للمرضى والجمهور بالمشاركة فى مواضيع الجودة ولكن تلك خدمة سطحيه أكثر من كونها مشاركة حقيقية.

D- هنالك رغبة وحماس حقيقين فى جميع انحاء المؤسسه من أجل التقدم المتواصل. كما هو معروف بأن التقدم المتواصل هو مسئولية الجميع وبأن المنظمة بكاملها والتى تشمل المرضى والعامة معنيين بهذه المسئولية.
تهدف هذه الهيئات أن تكون مراكزمتميزة يتم مقارنة ادائها مع المراكز الاخرى.
تضمين الاطباء الممارسين وملكيتهم لعملية المراجعة يؤدى الى التقدم المتواصل. تطوير البروتوكولات والسياسات ومراجعتها تتم من قبل العاملين ويتم استخدامها كاساس فى الرعاية والخدمات. يشارك المرضى والجمهور فى اتخاذ القرارات الداخلية-وهذا مما يجعلها مراكز خدمية ترتكز على المرضى.

E- غرس ثقافة التقدم المتواصل داخل االمؤسسه اساس اتخاذ القرار على كل المستويات.
وتعتبر المؤسسة مركز للاداء المتميز نتيجة للتقييم المتواصل للاداء مقارنة بمثيلاتها داخل وخارج الخدمة الصحية. تقوم الفرق بتصميم اجراء المراجعة بالتركيز على الناتج وبالتعاون مع المرضى والجمهور.
يكون العاملون فى يقظة تامة لاحتمال وجود مخاطر على السلامة.وهذا يعنى تقليص الحوجة للبروتوكولات والانظمة مع مرور الزمن عندها تصبح الممارسة المبنية على البرهان هى عامل طبيعى اضافة الى أن سلامة المريض تكون دائما ذات اولوية فى أذهان الجميع. وعلى هذا يكون المرضى والجمهور يتم تضمينهم بطريقة ذات معنى وروتينية فى المشاركة الداعمة والتغذية الراجحة.

2- **الاولوية للسلامة**

A-تعطى اولوية بسيطة للسلامة
هناك بعض انظمة ادارة المخاطر مثل الاستراتيجيات واللجان ولكن بدون مردود حقيقى. المؤسسة لا تعطى المخاطر الخاصة لها حيث يعتقدون أنه فى حالة وقوع أى حادثة تهدد سلامة المريض فان شركات التأمين سوف تكفلهم.

B- تصبح السلامة ذات أولوية فقط عند وقوع حادث ولكن فى بقية الوقت تكون الخدمة مجرد حديث فى الموضوع ما عدا عندما تتدخل السلطات القانونيه.
هناك اثبات ضعيف فى تنفيذ استراتيجية ادارة المخاطر .تناقش السلامة فى اداره المؤسسة و هدفها الحماية الذاتية وليس حماية المريض.

C- السلامة لها أولوية كافية وهنالك انظمة عديدة فى مكان الحماية.لكن هذه الانظمة ليست معممة على العاملين ولا تراجع. وليس لها مرونة فى الاستجابة للاحداث المخفية وتفشل فى التفاعل مع الامور المعقدة.
مسئولية ادارة المخاطر تستثمر فى شخص فردى لا يضمنها فى الهيئة الواسعة. مما يجعلها ثقافة مفروضة

D- ترتقى السلامة داخل الهيئة ويكون العاملين متحمسين فى الاشتراك فى أمور السلامة وعملياتها. المرضى والجمهور والهيئات الاخرى يشاركون فى ادارة المخاطر ومراجعتها. التدابير المتخذة تهدف لحماية المرضى ولا تهدف للحماية الذاتية.يتم تحديد المخاطر على نحو استباقى باستخدام تقييم المخاطر المنظورة واتخاذ الاجراءت اللازمة لاداراتها.هنالك حدود واضحة للمسائلة وحتى حين يأخذ أحد الافراد الريادة فى فى سلامة المرضى فى المؤسسة، وهذا هو الجزء الاساسى فى دور كل الاداريين.

E- السلامة لها الاولويه القصوى فى المؤسسة وينظر لمسؤلية السلامة كجزء من دور كل الافراد ويشمل ذلك المرضى والجمهور. يقيم العاملون المخاطر وينظرون للتقدمات الممكنة.سلامة المريض من الامور الساخنة
فى كل المؤسسة وتغرس فى ممارسات كل العاملين ابتداءا من مجلس الادرة والمدراء الى فرق الرعاية الصحية الذين لديهم احتكاك يومى مع المرضى، وذلك يشمل موظفى الدعم واشتراك المريض فى امور سلامة المريض ومراجعته لها مؤسس بطريقة مثلى.

3- أخطاء النظام والمسئوليات الفردية

A- يتم النظر الى الحوادث بأنها سوء حظ وخارجة عن سيطرة المؤسسة، وتحدث نتيجة لاخطاء العاملين أو سلوك المرضى. توجد ثقافة لوم قوية فى المؤسسة ويعرض الافراد لاجراءات توبيخية ولوم.

B- تنظر المؤسسة الى نفسها كضحية للظروف. وينظر للافراد كسبب ويكمن الحل فى اعادة التدريب والاجراءت الجزئية. عند وقوع الحادثة ليست هناك محاولة لدعم الجهات المعنية بما فى ذلك المرضى وأقاربهم.

C- هناك اعتراف بأن الانظمة تساهم فى الاحداث وليس الافراد فقط.وتقول الؤسسة بأن لها ثقافة الانفتاح العادل ولكن العاملين لا يشعرون بهذا.بروتكولات الانفتاح والانغلاق كتبت للتأكد من أن العاملون والمرضى وراعو المرضى يحصلون على الدعم عند الحوادث ولكنهم غير ملمين بالمعرفة عنها ولا باستخدامها.

D- الحوادث هى عبارة عن مزيج من أخطاء الافراد والانظمة. الؤسسة لها سياسة انفتاح تعاونية. ويتبع حادثة تهدد سلامة المريض، تحليل للانظمة مثل.وهذه العملية تخدم اتخاذ القرارات. عند توقيف العاملين وهناك نهج عادل وثابت فى التعامل مع أمور الموظفين بعد وقوع الحوادث. الؤسسة صريحة ومنفتحة مع المرضى ومقدم رعاية المرضى عند وقوع حادثة الحاق أذى أدت الى الحاق أذى جسيم أو موت، ولكنها لا تناقش كل انواع الحوادث.

E- يتم ملاحظة فشل النظام ويكون الموظفين على دراية تامة بمسؤلياتهم الشخصيةفيما يتعلق بالاخطاء والتبليغ بذلك. تمكن الانظمة المتكاملة فى تحليل الحوادث التى تهدد سلامة المريض والشكاوى والدعاوى القضائية
العاملون والمرضى وأقربهم يتعاونون بنشاط ولهم دعم من بداية الحادثة. المؤسسة لها مستوى عالى من الانفتاح والثقة. المؤسسة أيضا منفتحة ومخلصة مع المرضى ومقدمى الرعاية نحو جميع أنواع حوادث المرضى بغض النظر عن مستوى الضرر الواقع.

4- تسجيل الحوادث وأفضل السبل لذلك

A- توجد أنظمة مخصصة للتبليغ عن الحوادث ولكن الؤسسة فى حالة جهل تام الا فى حالة وقوع حادثة خطرة أو استلام رسائل من المحامين. تسود المؤسسة ثقافة اللوم العالية حيث يتعرض الافراد للاجراءات التأديبية ويصبحون ضحية للنظام.

B- هنالك نظام تبليغ للحوادث غير ناضج، ولكن الموظفين لا يشجعون للتبليغ عن الحوادث. تجمع معلومات دقيقة ولكن لا يتم تحليلها.هناك ثقافة لوم وعليه يكون الموظفين مترددين فى التبليغ عن الحوادث. عندما تقع الحوادث، ليست هناك محاولة لدعم الذين يشملهم الحادثة.

C- يوجد نظام مركزى للتبليغ عن الحوادث من غير الحاجة الى معرفة المبلغ ويركز على تعبئة الاستمارات. هناك محاولات بغرض تشجيع الموظفين والمرضى للتبليغ عن الحوادث (ويشمل ذلك الحوادث التى منعت أو التى منعت أو التى لم تؤدى الى أى أضرار) على الرغم من ذلك فان الموظفين لا يشعرون بالامان والمرضضى لا يشعرون بالارتياح عند التبليغ عن هذه الحوادث. تعتمد المؤسسة مصادر أخرى لمعلومات السلامة جنبا الى جنب مع تقارير الحوادث (مثل المراجعات والشكوى).

D- التبليغ عن حوادث سلامة المريض على كل المستويين المحلى والوطنى (مثال نظام القومى لتقديم التقارير والتعليم) وينظر له كفرص تعليمية. يوجد سبل تبليغ للموظفين والمرضى سهلة، وتسمح اختيار الاتجاهات المختلفة. الموظفون يشعرون بالاطمئنان عند تبليغ كل الحوادث التى تهدد سلامة المرضى ويشمل الحوادث الت يمكن تجنبها. الموظفون والمرضى ومقدمى الرعاية مدعمون منذ لحظة التبليغ.

E- التبليغ عن حوادث سلامة المريض عند الموظفين أمر طبيعى(ويشمل ذلك الحوادث التى لم تؤدى الى أضرار أو التى منعت) وللموظفين ثقة فى عمليةالاستقصاء ويتفهموا قيمة التبليغ لكل من الانظمة المحلية والقومية(مثال النظام القومى لتقويم التقارير والتعليم).

يشجع المرضى بالتبليغ عن الحوادث. وهى مؤسسة تعليمية وفيها أنظمة متينة لتدوين الممارسة المثلى ومكملاتها.

5- تقييم الحوادث والممارسة الجيدة

A- توضع الحوادث والشكوى تحت البساط ما أمكن. ويتم التحقيق فى الحوادث بطريقة سطحية بواسطة صغار المدراء بهدف قفل الموضوع . تجمع معلومات التحقيق وتخزن ويؤخذ اجراء بسيط عدا الاجراء الاداري (المحاكمة على الملأ) ومحاولات التصدى للاعلام . فى هذه المؤسسة هناك اعتراف ضئيل بسلامة الممارسات الجيدة.

B- توجه التحقيقات بهدف الحد من الاضرار فى المؤسسة وتوزيع اللوم على الافراد. التحقيقات سطحية وتركز على حالة معينة وأفعال فردية. تقترح الحلول السريعة والتى تتعامل مع حادثة معينة ولكنها لا تحتمل أن توجه اذا زالت حدة الحادثة. وبعض التحقيقات تظل غير مكتملة.

C- الاداريون الكبار يشاركون فى التحقيق والذى يكون فى نطاق ضيق ويتم التركيز فيه على الافراد والانظمة المحيطة بالحادث. هناك اجراء مفصل لعملية التحقيق، والتى تشمل تعبئة استمارات عديدة ولا يجري التحقيق الى حد ما لفحص جذور المشكلة ودعم من يشمله الحادث ولكن كاجراء اداري ولاسترضاء المرضى ومقدمى الرعاية.الموظفون يحفزوا لمراجعة الاجراءات وكيفية تنفيذها ولكن عملية التعليم متضاربة.

D- المؤسسة مفتوحة للاستفسارات وترحب بالمشاركة الخارجية للتحقيقات من أجل تحقيق نظرة مستقلة. الموظفون المتطورتين فى الحوادث يتم شملهم فى التحقيق لتحديد جذور المشكلة والقضايا التى فى الواجهة.

الهدف من التحقيقات هو الاستفادة والتعلم من الحوادث ونشر النتائج على نطاق واسع. تستخدم البيانات منةتقرير الحوادث فى تحليل الظواهر، تحديد النقاط الساخنة ودراسة الاثار المترتبة على التدريب. وهى مؤسسة منفتحة ذات نظرة مستقبلية. المرضى يشاركون فى عملية التحقيق ورؤيتهم وتجربتهم وتوصياتهم مطلوبة.

E- تجرى المؤسسة تحقيقات مستقلة للحادث على الصعيدين الداخلى والخارجى وتشمل الموظفين والمرضى المعنيين. وينظر الى التحقيقات فى الحوادث كفرص للتعلم وتركز على التقدم وتشمل توصيات المرضى . تراجع عملية تحليل الحادث بطريقة منهجية ويتم مراجعتها بانتظام بعد التشاور مع الموظفين.

التعلم من الممارسة الجيدة مشتركة فى جميع انحاء المنظمة وعلى المستوى القومى. هى مؤسسة تعلم كما يتضح من الالتزام للتعلم من الحوادث فى جميع المستويات من المجلس وكبار المدراء ومن خلال فرق الرعاية الصحية وموظفى الدعم.

6- التعلم واحداث التغير

A- لا تبذل محاولات للتعلم من الحوادث عدا تلك التى تفرضها جهات خارجية مثل المساءلات الحكومية.

الهدف بعد الحادثة هو تغطية التقصير وحماية المؤسسة. وتعتبر المؤسسة أنها قد نجحت عندما تصبح وسائل الاعلام عديمة المعرفة بالحادث. لا يتم أى تعديلات عقب الحادثة بغض النظر عن تلك الموجهة الى الافراد المعنيين.

B- يوجد التعليم التنظيمى ولو قليلا وما يحدث يكون ذو علاقة لدرجة الاضطراب الذى تضرر منه كبار الموظفين. وجميع التعليم مخصص كحادثة معينة.

وكل التغييرات المبادرة عقب حدوث الحادث ليست دائمة بل هى ردود فعل للاخطاء الفردية الملاحظة ويتم وضعها وفرضها من كبار الموظفين. وبالتالى فان الحوادث المماثلة من المتوقع تكرارها.

C- هناك بعض النظم لتسهيل التعلم المؤسسى وهذه قد تشمل وضع وجهة نظر المريض فى الاعتبار الدروس المستفادة لا تعمم على المؤسسة. وتحاك بعض التغييرات القصرية ولكنها متصلة مباشرة بحادثة معينة.

اللجان والمدراء يتخذون القرارات تجاه استحداث التغييرات ولكن عدم تضمين الموظفين يؤدى لعدم دمج هذه القرارت فى أنماط العمل.

يتم شمل المرضى حتى تثبت المؤسسة للمنظمين أن لديها بعض الالتزام نحو مشاركة المريض والجمهور.

D- للمؤسسة ثقافة تعليمية ولديها عمليات لتشارك فى التعلم مثل التفكير ومشاركة تصور المريض.
هناك دعم من مجلس الادارة لتفعيل التحقيقات العميقة والدفع لتغيرات تعالج الاسباب الكامنة للحوادث. يشارك الموظفون بنشاط فى العملية وهنالك التزام حقيقى نحو التغيير الدائم فى جميع أنحاء المؤسسة.
المؤسسة تبعث فى الافق عن الفرص التعليمية وهى حريصة على التعلم من تجارب الاخرين. التعلم التنظيمى عقب الخوادث يستخدم فى التخطيط للمستقبل. وهى مؤسسة منفتحة ولها ثقة بنفسها.

E- هى مؤسسة تعليمية. وتتعلم المؤسسة من المعلومات والخبرات الداخلية والخارجية وهى ملتزمة لاشراك من هو خارج وداخل المؤسسة فى هذا التعلم.
تتم مناقشة الحوادث التى تهدد سلامة المريض (وهذا يشمل تلك التى منعت) فى محافل مفتوحة حيث يتم تمكين الموظفين فى المشاركة. يتم تقدير التعليم التنظيمى والفردى على حد السواء.
يحدث التقدم فى الممارسة من دون التأثر بحادث حيث أن الثقافة هى من نوع التقدم المستمر. ويلعب المرضى دورا اساسيا فى التعلم ويساهمون فى عمليات التغيير اللاحقة.

7- التواصل فى مواضيع السلامة

A- لتواصل بصفة عامة ضعيف ويبدأ من الأعلى الى الاسفل والموظفين غير قادرين على التحدث الى مدرائهم حول المخاطر ويتم الاحتفاظ بالاحداث داخليا ولا يتحدث عنها.
المؤسسة منغلقة فى الاساس وهنالك تواصل سلبى يرتكز على اللوم ويعطى المرضى المعلومات المطلوبة قانونيا فقط ويعد بذل جهد كبير حتى يتاح لهم الوصول اليها.

B- التواصل عامة توجيهى ويأتى باصدار تعليمات من المدراء والموظفين قادرين فقط فى الحديث الى من يرئسوهم بعد حدوث خطأ ما. التواصل غير مخصص ويقتصر على الذين يشملهم حادث معين ويعطى المريض المعلومات التى تشعر المؤسسة بأنها مناسبة فى اتجاه تواصل أحادى.

C- هنالك استراتيجية للتواصل كما توجد سياسات واجراءات تحفظ الكثير من السجلات. هناك الكثير من المعلومات التى يتم جمعها من الموظفين والمرضى والمؤسسات الاخرى ولكنها ليست مستخدمة بشكل فعال وهذا يؤدى لتكدس المعلومات مما يعنى أن مأنجز فى الواقع قليل بالمقرنة مع المعلومات الواردة من الموظفين. ويوجد نظام للتواصل بشأن المخاطر ولكن لا يتحقق أحد من أنه يعمل.

D- يخضع نظام الاتصال والسجلات للمراجعة بشكل دائم. ويوجد اتصال عبر المؤسسات لتسيير وضع المقاييس بطريقة ذات معنى.
الموظفون من كل المستويات يشاركون وتتاح لهم اليات التغذية الراجعة للمؤسسة.
تتم المشاركة بالمعلومات وهناك محاضرات تقدم بانتظام يشجع فيها الموظفين بتحديد جدول الاعمال. يتم اتصال فعال مع المرضى والجمعيات بخصوص أمور السلامة.

Eيشارك الجميع فى نقل أمور السلامة ويتعلمون من تجارب الاخرين (الجيدة والسيئة). هى مؤسسة ذات شفافية وتشمل مشاركة المرضى فى تطوير سيلسة ادارة المخاطر.
يتم تشجيع الافكار المبتكرة ويتم تمكين الموظفين لتنفيذها.
هى مؤسسة تنقل الممارسة الجيدة للداخل والخارج

8- ادارة شئون العاملين وأمور السلامة

A- ينظر الى العاملين كافراد لملئ الوظائف فقط. وعمليات اختيار الموظفين وتوظيفهم عملية بدائية. الاستخدام اللغوى سلبى وينظر الى التدنى الصحى وسجلات الحضور كأداة تأديبية. يشعر الموظفين بأنهم غير مدعومين ويروا شئون العاملين (كالاخر) وليس (كنحن). هناك سياسة موظفين بدائية وليس هناك برامج تنمية موارد بشرية ولا توجد هناك اى صلات مع الصحة المهنية.

B- يتغير الوصف الوظيفى ومستويات التوظيف استجابة للمشاكل فقط، وعليه يكون هنالك اختيار جيد وسياسات استبقاء فى الاماكن التى تعرضت فى الماضى للمشاكل. بيئة العمل مفعمة باللوم والعتاب. ودعم الموظفين متاح ولكنه ضئيل ورمزى. توجد سياسة للموارد البشرية متواضعة ولكنها غير مرنة وطورت استجابة للمشاكل السابقة.

C- توجد اجراءات توظيف واستبقاء ودائما يتم مراجعة المؤهلات. واللغة المستخدمة فى ادارة الموظفين بصفة عامة رسمية ومحايدة وتحكمها السياسات والاجراءات. اليات دعم الموظفين يحكمها الكثير من البروقراطية وخطط العمل. هنالك اجراءات تقييم وتنمية الموظفين والصحة المهنية ولكن يتم تطبيق ذلك بطريقة صارمة وعليه لا تحقق دائما ما صممت لأجله. ينظر الى هذه الاجراءات من قبل الادارة كأداة للسيطرة على الموظفين.

D- يوجد التزام نحو مجانسة الافراد للوظائف. وهناك محاولات لفهم لماذا يحدث سوء الاداء ويوجد هناك نظام دعم مرن وواضح، تم تفصيله وفقا لاحتياجات الفرد. تراجع عمليات ادارة شئون الموظفين عند الضرر كما يتم اجراء التغيرات اللازمة. هنالك اهتمام حقيقى حول صحة الموظفين ونظام التقييم والمراقبة والمراجعة.
يتم السعى بنشاط نحو مساهمة المرضى ومقدمى الرعاية بشأن التوظيف.

Eيستخدم اطار المعرفة والمهارت لتصميم مواصفات الوظيفة ولتمييز الكفاءات. التفكير الملئ والمراجعة (سواء كانت ايجابية أو سلبية) تحدث بطريقة مستمرة وتلقائية.
المؤسسة لها التزام نحو موظفيها، والجميع لديه الثقة فى اجراءات شئون العاملين والتى تشمل الارشاد والاشراف.
المرضى والجمهور لهم مشاركة ذات معنى فى وضع وتنفيذ أى سياسات تتعلق بالسلامة وقضايا التوظيف. شئون العاملين ليست كيانا مستقلا ولكنها جزءا مكملا للمؤسسة.
تستخدم أنظمة التحليل اثر وقوع الحادثة التى تهدد سلامة المريض عند اتخاذ القرارات نحو المساهمة النسبية لعوامل الانظمة.
دور الفرد الموظف فى الرعاية الصحية. هذه العملية تخدم القرارات بشأن توقيف الموظفين وعلى هذا النحو يكون هناك نهج ثابت وعادل للتعامل مع قضايا الموظفين بعد وقوع الحادث.

9-تعليم وتدريب الموظفين

A- التدريب له أولوية ضعيفة. ويقدم فقط التدريب الذى تطلبه الحكومة.
تنظر الادارة الى تعليم الموظفين كبرنامج مزعج ومكلف ومضيعة للوقت. وبالتالى لا يوجد هنالك ضبط بشأن النوعية أو صلة للتدريب والتعليم المتلقى فيما يتعلق بالتطوير المهنى للموظفين. ينظر الى الموظفين باعتبار أنهم مدربين للقيام بعملهم وعليه لماذا يحتاجون لمزيد من التدريب.

B- يحدث التريب حيث هنالك مشاكل معينة ولها علاقة بشكل كامل على المناطق ذات المخاطر العالية حيث يتم ملئ الثغرات.
هى مسئولية الفرد أن يقرأ ويتصرف ويقوم بتمويل احتياجاته التعليمية.
يرتكز التعليم والتدريب على زيادة الدخل وحماية ظهر المؤسسة بدلا من التطوير المهنى للموظفين. ليس هناك ميزانية مخصصة للتدريب ويحدث تقييم الموظفين بصورة.....

C- يعكس برنامج التدريب الاحتياجات التنظيمية وعليه يدعم التدريب فقط اذا كان يفيد المؤسسة. ولا يوجد تفكير جاد فى اشراك المرضى فى التدريب.
توجد خطط تنموية شخصية متواضعة بحيث يكون لكل شخص ملفه الخاص. ولكن هذا ليس ذو فعالية ومصدره غير مناسب ولا يعطى أولوية.
معروض عدد كبير من الدورات ولكن ليست كلها ذات علاقة بالتطوير الوظيفى ولا يتوقع أن يستفيد منها الموظفين. ينظر الى التدريب كوسيلة لمنع وقوع الاخطاء وتقييم الموظفين يرتكز حول هذا الامر.

D- هنالك محاولات لتحديد احتياجات التدريب للمؤسسة و احتياجات الافراد و تناغمها. يتم التخطيط للفرص التعليمية جيدا وتسخر لها الموارد وهى متاحة من والى كل الوكالات ذات الصلة.
وينظر للتعليم والتدريب كأساس للتطوير الوظيفى للفرد ويرتبط مباشرة بالنظم التنظيمية الاخرى مثل التبليغ عن الحادث.
يركز التقييم الوظيفى على الموظفين ويتم بنائه على احتياجات الفرد.
المحاولات أولية لاشراك المرضى والجمهور فى تدريب الموظفين جارية وبدأت المؤسسة فى فهم الدروس من تجاربهم.

E- الافراد يتم تمكينهم وحثهم للقيلم أو تولى أمر تحليل احتياجاتهم ومناقشة برامجهم التدريبية. يحدث التعلم بشكل يومى ولا يقتصر فقط على البيئة الصفية.
ينظر الى التعلم كأساس للثقافة التنظيمية. النهج المتبع فى التدريب والتعليم مرن وينظر اليه كأسلوب لدعم الموظفين حتى يدركوا امكانياتهم. يبدأ التقييم ويتم ادارته بواسطة الموظفين.
يشارك المرضى فى تدريب الموظفين للمساعدة فى فهم تصور المريض عن المخاطر والسلامة.

10- العمل كفرق

A- يعمل الافراد فى الغالب فى عزلة ولكن حينما يكون هنالك فرق فان أفرادها يكونوا أحادي التخصصات مع الاختلال الوظيفى.
يوجد توتر بين أعضاء الفريق وهناك بناء وظيفى صارم مبنى على الرتب. هى أشبه ماتكون مجموعة مجموعة من الناس جمعوا تحت توجيه زعيم اسمى. المعلومات لا يتم تبادلها بين أعضاء الفريق و يعمل الفريق بسرية.

B- يعمل الناس فقط كفريق اثر الحدث السلبى واستجابة للمطالب الخارجية. والافراد حقيقة غير ملزمين بالفريق. هنالك تسلسل وظيفى مبنى على الرتب فى كل فريق، مطابق للتسلسل الوظيفى للمنظمة ككل. هناك فرق متعددة التخصصات ولكن أملى عليهم

بأن يعملوا معا، والخدمة المثالية لفريق العمل مجرد حديث فقط. تتوالى العلومات الى أعضلء الفريق عقب كل حادثة. تعمل الفرق بطريقة دفاعية والاعضاء الجدد غير مرحب بهم.

C- وضعت الفرق متعددة التخصصات مع بعض الاستجابة للسياسات الحكومية. ولكن لا توجد وسيلة لقياس مدى فعاليتها. ينظر الى العمل كفرق من قبل الصفوف الامامية للموظفين كحديث. تعطى الفرق كميات من المعلومات المدونة حول الكيفية التى يجب العمل بها. توجد اليات رسمية للمشاركة فى الافكار والمعلومات داخل وعبر الفرق ولكنها لا تستخدم بطريقة فاعلة. فرق العمل تعمل وراء الكواليس ولا تتعدى المؤسسة الواحدة.

D- هناك فرق متعددة التخصصات وتسخر الموارد والوقت لتنمية عمليات الفرق. بنية الفريق سلسة حيث يتناول الناس الادوار بالطريقة المناسبة لهم فى ذات الوقت. يوجد تقييم عن فعالية الفريق وتجري التغييرات عند الحاجة. الفرق متعاونة وقابلة للتأقلم. الفرق منفتحة ومن المحتمل اشراك أعضاء من خارج المؤسسة.

F- يقدم تدريب دوري ومقيم فى ادارة موارد الفرق للفرق متعددة التخصصات المتكاملة. عضوية الفريق مرنة وبنيتها أفقية. مختلف الناس يؤدون مساهمات قيمة عند الحاجة. الفرق مبني على التفاهم والرؤية المشتركة بدل من القرب الجغرافى. العمل كفريق هو الوسيلة المقبولة فى المؤسسة. الفرق منفتحة محليا ويشلرك فيها الاعضاء من مختلف المؤسسات المحلية والوطنية والعالمية.

Appendix 3.3 FINAL ENGLISH VERSION THE MAPSAF

An exploratory Study into patient safety culture using MaPSaF

Commitment to overall continuous improvement	
A	No resources are invested in the identification of problems or areas of good practice. If any auditing occurs it lacks structure and there is no response to what is discovered. Whatever protocols or policies exist are there to meet the organisation's statutory requirements and are not used, reviewed or updated. Poor quality care is tolerated or ignored. This attitude is evident at Board level and throughout the organisation in the healthcare teams.
B	A continuous improvement framework is developed in response to specific directives or an imminent inspection visit. Auditing only occurs in response to specific incidents and national directives and does not reflect local needs. Little attempt is made to respond to any audit findings. The bare minimum of protocols and policies exist and these tend to be out-of-date and unused unless an incident occurs that triggers their review. Development of new protocols and policies occurs in response to incidents and complaints.
C	Frontline staff are not engaged in the improvement process and they see it as a management activity that is externally driven. Lots of auditing occurs but lacks an overall strategy linking with organisational or local needs. Staff are overloaded with protocols and policies (which are regularly reviewed and updated) that are rarely implemented. Patients and the public may be involved in quality issues but this is empty talk rather than real engagement.
D	There is a genuine desire and enthusiasm throughout the organisation for continuous improvement. It is recognised that continuous improvement is everyone's responsibility and that the whole organisation, including patients and the public, need to be involved. Such organisations aim to be centres of excellence and compare their performance against that of others. Clinicians are involved in, and have ownership of, the auditing process which leads to continuous improvement. Protocols and policies are developed and reviewed by staff and are used as the basis for care and service provision. Patients and the public are formally involved in internal decisions – making it a patient centred service.
E	A culture of continuous improvement is embedded within the organisation and is integral to decision making at all levels. The organisation is a centre of excellence, continually assessing and comparing its performance against others both within and outside the health service. Teams design and conduct their own outcome focused audit programme, in collaboration with patients and the public. Staff are alert to potential safety risks. This means that over time the need for protocols and policies is reduced as evidence-based practice is second nature and patient safety is constantly on everyone's mind. Patients and the public are involved in a routine, meaningful way with ongoing contribution and feedback.

Priority given to safety	
A	A low priority is given to safety. There are some risk management systems in place, such as strategies and committees, but nothing is actually delivered. This is an organisation unaware of their risks, believing that if a patient safety incident occurs, insurance schemes can be used to help out.
B	Safety becomes a priority once an incident occurs, but the rest of the time only empty talk is paid to the issue apart from meeting legal requirements. There is little evidence of any implementation of a risk management strategy. Safety is only discussed by the Board in relation to specific incidents. Any measures that are taken are aimed at self-protection and not patient protection. In order to meet financial constraints or government set targets, risks are taken.
C	Safety has a fairly high priority and there are numerous systems (including those integrating the patient point of view) in place to protect it. However, these systems are not widely disseminated to staff or reviewed. They also tend to lack the flexibility to respond to unforeseen events and fail to capture the complexity of the issues involved. Responsibility for risk management is invested in a single individual who does not integrate it within the wider organisation. It is an imposed culture.
D	Safety is promoted throughout the organisation and staff are actively involved in all safety issues and processes. Patients, the public and other organisations are also involved in risk management systems and their review. Measures taken are aimed at patient protection and not self-protection. Risks are proactively identified, using prospective risk assessments, and action is taken to manage them. There are clear accountability lines and while one individual takes the lead for patient safety in the organisation, it is a key part of all managers' roles.
E	Safety is the top priority in the organisation, and responsibility for safety is seen as being part of everyone's role including patients and the public. Staff constantly assess risks and look for potential improvements. Patient safety is a high profile issue throughout the organisation and is embedded in the activities of all staff, from the Board/senior managers through to healthcare teams who have day-to-day contact with patients, including support staff. Patient involvement in, and review of, patient safety issues is well established.

System errors and individual responsibility	
A	Incidents are seen as 'bad luck' and outside the organisation's control occurring as a result of staff errors or patient behaviour. There is a strong blame culture with individuals subjected to persecution and disciplinary action.
B	The organisation sees itself as a victim of circumstances. Individuals are seen as the cause and the solution is retraining and disciplinary action. When incidents occur there is no attempt to support those involved, including the patients and their relatives.
C	There is a recognition that systems contribute to incidents and not just individuals. The organisation says that it has an open and fair culture but it is not perceived in that way by staff. Being open/open disclosure protocols have been written to ensure that staff and patients/carers receive support following an incident do exist, but they are not widely known about or used.
D	It is accepted that incidents are a combination of individual and system faults. The organisation has an open, fair and collaborative culture. Following a patient safety incident, a systems analysis is carried out and used to make decisions about the relative contribution of systems factors and the individual. This process informs decisions about staff suspensions and so there is a consistent and fair approach to dealing with staff issues following incidents. The organisation is also open and honest with patients and/or their carers when a patient safety incident occurs that led to severe harm or death, but does not discuss all types of incidents.
E	It is accepted that incidents are a combination of individual and system faults. The organisation has an open, fair and collaborative culture. Following a patient safety incident, a systems analysis is carried out and used to make decisions about the relative contribution of systems factors and the individual. This process informs decisions about staff suspensions and so there is a consistent and fair approach to dealing with staff issues following incidents. The organisation is also open and honest with patients and/or their carers when a patient safety incident occurs that led to severe harm or death, but does not discuss all types of incidents.

Recording incidents and best practice	
A	Purpose designed incident reporting systems are in place but the organisation is largely in 'blissful ignorance' unless serious incidents occur or solicitors' letters are received. There is a high blame culture, with individuals subjected to persecution and disciplinary action. No learning can occur.
B	There is an embryonic incident reporting system, although staff are not encouraged to report incidents. Minimal data on the incidents is collected but not analysed. There is a blame culture, so staff are reluctant to report incidents. When incidents occur, there is no attempt to support any of those involved.
C	A centralised anonymous reporting system is in place with a lot of emphasis on form completion. Attempts are made to encourage staff and patients to report incidents (including those that were prevented or led to no harm) though staff do not feel safe and patients do not feel comfortable reporting them. The organisation considers other sources of safety information alongside incident reports (e.g. complaints and audits).
D	Reporting of patient safety incidents at both a local and national level is encouraged and they are seen as learning opportunities. Accessible, 'staff and patient friendly' reporting methods are used, allowing trends to be readily examined. Staff feel safe reporting all types of patient safety incidents, including those that were prevented. Staff, patients and/or their careers are supported from the moment of reporting.
E	It is second nature for staff to report patient safety incidents (including those that led to no harm or were prevented) as they have confidence in the investigation process and understand the value of reporting to both local systems and nationally. Patients are actively encouraged to report incidents. It is a learning organisation and robust systems exist in order to record best practice and compliments.

Evaluating incidents and best practice	
A	Incidents and complaints are 'swept under the carpet' if possible. Incidents are superficially investigated by a junior manager with the aim of 'closing the book'. Information gathered from the investigation is stored but little action is taken apart from disciplinary action ('public executions') and attempts to manage the media. In this organisation there is little recognition of good safe practice.
B	Investigations are instigated with the aim of damage limitation for the organisation and apportioning individual blame. Investigations are cursory and focus on a specific event and the actions of an individual. Quick-fix solutions are proposed that deal with the specific incident, but may not be instigated once the 'heat is off'. Some investigations are not completed.
C	Senior managers are involved in the investigation, which is narrow and focuses on the individuals and systems surrounding the incident. There is a detailed procedure for the investigation process, which involves the completion of multiple forms – the investigation is conducted for its own sake and to placate patients/carers rather than examine root causes and support those involved. Staff are motivated to review procedures or how the procedures are implemented, but learning is variable.
D	The organisation is open to inquiry and welcomes external involvement in investigations in order to gain an independent perspective. The staff involved in incidents are involved in their investigation to identify root causes and interface issues. The aim of investigations is to learn from incidents and disseminate the findings widely. Data from incident reports are used to analyse trends, identify 'hot spots' and examine training implications. It is a forward-looking, open organisation. Patients are involved in the investigation process and their perceptions, experience and recommendations sought.
E	The organisation conducts both internal and external independent incident investigations that include the staff and patients involved. Incident investigations are seen as learning opportunities and focus upon improvement and include patient recommendations. The incident analysis process is systematically and regularly reviewed following consultation with all staff. Learning from best practice is shared across the organisation and nationally. It is a learning organisation as evidenced by a commitment to learn from incidents throughout all levels – from the Board/senior managers through to healthcare teams and support staff.

Learning and effecting change	
A	No attempts are made to learn from incidents unless imposed by external bodies such as public enquiries. The aim after an incident is to protect itself – the organisation considers that is has been successful when the media do not become aware of incidents. No changes are instigated after an incident apart from those directed at the individuals concerned.
B	Little, if any, organisational learning occurs and what does take place relates to the amount of disruption that senior staff have experienced. All learning is specific to the particular incident. Any changes instigated in the aftermath of an incident are not sustainable as they are knee-jerk reactions to perceived individual errors and are devised and imposed by senior managers. Consequently, similar incidents tend to recur.
C	Some systems are in place to facilitate organisational learning and this may include consideration of the patient perspective. The lessons learned are not disseminated throughout the organisation. Some enforced local changes relating directly to the specific incident are made. Committees and managers decide on any changes to be introduced, but lack of staff involvement leads to them not being integrated into working patterns. Patients are only involved so the organisation can prove to regulators that they have some commitment to patient and public involvement.
D	The organisation has a learning culture and processes exist to share learning, such as reflection and sharing patient points of view. There is Board/senior management support for in-depth incident investigations, and changes instigated address underlying causes (e.g. systems factors). Staff are actively involved in the process and there is a real commitment to sustainable change throughout the organisation. The organisation 'scans the horizon' for learning opportunities and is keen to learn from others' experiences. Organisational learning following incidents is used in forward planning. It is an open, self-confident organisation.
E	It is a learning organisation. The organisation learns from internal and external information and experience and is committed to sharing this learning both within and outside the organisation. Patient safety incidents (including those that led to no harm or were prevented) are discussed in open forums where all staff are empowered to contribute. Both individual and organisational learning is evaluated. Improvements in practice occur without the trigger of an incident as the culture is one of continuous improvement. Patients play a key role in learning and contribute to subsequent change processes.

Communication about safety incidents	
A	Communication in general is poor; it comes from the top down and staff are not able to speak to their managers about risk. Events are kept in-house and not talked about. The organisation is essentially closed. What communication there is, is negative, with a focus on blame. Patients are only given information which must be legally provided and only after exerting a lot of pressure on the organisation to give them access.
B	Communication in general is directive with managers issuing instructions. Staff are only able to speak to their managers after something has gone wrong. Communication is purpose designed and restricted to those involved in a specific incident. The patient is given the information the organisation feels is appropriate in a one-way communication.
C	There is a communication strategy. Policies and procedures are in place, and lots of records are kept. There is a lot of information collected from staff, patients and other organisations but it is not effectively utilised. This leads to an information overload meaning that little is actually done with the information received by staff. A risk communication system is in place, but no-one checks whether it is working.
D	The communications system and record keeping are fully audited. There is communication across organisations facilitating meaningful benchmarking. All levels of staff are involved, and there are robust mechanisms for them to feedback to the organisation. Information is shared, there are regular briefing sessions where staff are encouraged to set the agenda. Effective communication regarding safety issues is made with patient and public involvement.
E	Everybody communicates safety issues and learns from the experiences of others (good and bad). It is a transparent organisation and includes patient participation in risk management policy development. Innovative ideas are encouraged and staff are empowered to implement them. This is an organisation that communicates good practice both externally and internally.

Personal Management and safety issues	
A	Staff are seen just as bodies to fill posts. Recruitment and selection processes are rudimentary. The language used is negative and poor health and attendance records are seen as disciplinary matters. Staff feel unsupported and see Personnel as 'them' and not 'us'. There is an underdeveloped staff policy, no structured HR development programme and no links with occupational health.
B	Job descriptions and staffing levels change only in response to problems, so there are good selection and retention policies in areas where the organisation has been vulnerable in the past. The atmosphere is of blame and punishment. Staff support is available, but is minimal and tokenistic. There is a very basic HR policy, but it is inflexible and developed in response to problems that have already been experienced.
C	Recruitment and retention procedures are in place and qualifications are always checked. The language used to manage staff is generally formal and neutral and guided by policies and procedures. Mechanisms for staff support are governed by a lot of paperwork and policies. The procedures on appraisal, staff development and occupational health are there but are inflexibly applied, and so do not always achieve what they were designed for. These procedures are seen as a tool for management to control staff.
D	There is some commitment to matching individuals to posts. There are attempts to understand why poor performance occurs, and visible, flexible support systems exist tailored to the needs of the individual. Personnel management processes are reviewed and changes are made when necessary. There is genuine concern about staff health, and good systems of appraisal, monitoring and review. Patient/carer input on safety and staffing issues is actively sought. There is demonstrable evidence of proactive measures taken in some areas.
E	Job specifications are designed to identify competencies using a Knowledge and Skills Framework. Reflection and review (both positive and negative) occur continuously and automatically. The organisation is committed to its staff, and everyone has confidence in the personnel management procedures that include mentorship and supervision. Patients and the public have meaningful involvement in the development and implementation of any policies related to safety and staffing issues. Personnel management is not a separate entity but an integral part of the organisation. Following a patient safety incident, a systems analysis is used to make decisions about the relative contribution of systems factors and the individual healthcare professional. This process informs decisions about staff suspensions and as such there is a consistent and fair approach to dealing with staff issues following incidents.

Staff Education and Training	
A	Training has a low priority. The only training offered is that required by government. Staff education is seen by management as irritating, time consuming and costly. There are consequently no checks made on the quality or relevance of any education or training given with regards to career development of staff. Staff are seen as already trained to do their job, so why would they need more training?
B	Training occurs where there have been specific problems and relates almost entirely to high risk areas where obvious gaps are filled. It is the responsibility of the individual to read, act upon and fund their own educational needs. Education and training focus on maximising income and covering the organisation's back rather than the career development of the staff. There is no dedicated training budget and staff appraisals occur for specific purposes.
C	The training programme reflects organisational needs so training is supported only if it benefits the organisation. No thought is given to actively involving patients in training. Basic Personal Development Plans are in place so everyone has their own file. However, these are not very effective as they are not properly resourced or given priority. There are a large number of courses on offer, however not all of these are relevant to the career development of the staff expected to make use of them. Training is seen as the way to prevent mistakes and appraisals are focused around this.
D	There is an attempt to identify the training needs of the organisation, and of individuals, and to match them up. Educational opportunities are well planned and resourced and are available from and for all relevant agencies. Training and education are seen as integral to the career development of individuals and are linked directly to other organisational systems, such as incident reporting. Appraisals are staff centred and are built around the needs of the individual. Preliminary attempts to involve patients and the public in staff training are underway and the organisation is starting to learn lessons from their experiences.
E	Individuals are empowered and motivated to undertake their own training needs analysis and negotiate their own training programme. Learning is a daily occurrence and does not happen solely in a classroom environment. Education is seen as being integral to the organisational culture. The approach to training and education is flexible and seen as a way of supporting staff in fulfilling their potential. Appraisals are initiated and managed by the staff themselves. Patients are involved in staff training to aid understanding of patient perceptions of risk and safety.

Team working	
A	Individuals mainly work in isolation but where there are teams they are unit-disciplinary and dysfunctional. There are tensions between the team members and a rigid hierarchical structure. They are more like a collection of people brought together under the direction of a nominal leader. Information is not shared between team members. The team operates secretively.
B	People only work as a team following a negative event and to respond to external demands. Individuals are not actually committed to the team. There is a clear hierarchy in every team, corresponding to the hierarchy of the organisation as a whole. There are multidisciplinary teams, but they have been told to work together, and only empty to the ideals of team working. Information is cascaded to team members following an incident. The team operates defensively and newcomers are not welcomed.
C	Multidisciplinary teams are put together to respond to government policies, but there is no way of measuring how effective they are. Teamwork is seen by lower grades of staff as empty talk to the idea of empowerment. Teams are given lots of written information about how they should function. There are official mechanisms for the sharing of ideas or information within and across teams but these are not used effectively. Teams operate behind the scenes and generally within a single organisation.
D	Teams are multidisciplinary and time and resources are devoted to team development processes. Team structure is fluid, with people taking up the role most appropriate for them at the time. There is evaluation of how effective the team is and changes are made when necessary. Teams are collaborative and adaptable. Teams are open and may involve members external to the organisation
E	Regular and evaluated team resource management training is offered to fully integrated multidisciplinary teams. Team membership is flexible with a horizontal structure. Different people make equally valued contributions when appropriate. Teams are about shared understanding and vision rather than geographical proximity. Team working is the accepted way in the organisation. Teams are totally open, involving members from diverse organisations, locally, nationally and even internationally.

Appendix 3.4 PARTICIPANT INFORMATION LEAFLET FOR PATIENT SAFETY CULTURE FOCUS GROUPS- ARABIC

An exploratory Study on patient safety culture using focus group discussion based on the Manchester Patient Safety Framework

معلومات المشروع البحثى

ماهو الغرض من هذا المشروع البحثى؟

- هذا المشروع يهدف الى معرفة انظمة سلامة المرضى المتبعه فى المستشفى .

لماذا تم اختيارك للمشاركة فى هذا المشروع البحثى؟

- لقد تم التعرف على اسمك وتم اختيارك من سجلات العاملين بالمستشفى.

ماهى الاشياء التى تنطوى على المشاركة فى هذا المشروع البحثى؟

- يتطلب منك المشاركه فى مجموعات نقاش عن الانظمه المتبعه بخصوص سلامة المرضى.
  سيتضمن تسجيل النقاش عبر مسجل رقمى وذلك لاثراء عملية البحث والتاكد من شمولية النقاط التى اثبرت اثناء االنقاش .المشاركة فى هذا المشروع البحثى اختيلرية ولن تؤثر على عملك وترقيتك فى المستشفى

ماذا أفعل اذا كنت أرغب فى المشاركة؟

- اذا كنت ترغب فى المشاركة فى هذا المشروع البحثى فما عليك الا التوقيع فى استمارة الموافقة وتسليمه لدكتوره علياء فيصل بالصيدلية.

ماذا أفعل اذا لم اكن أرغب فى المشاركة؟

- اذا كنت اتخذت قرارك بعدم المشاركة فى هذا المشروع البحثى فما عليك الا ان ترجع الاقرار من غير امضاء.

ماذا أفعل اذا لم اكن متأكدا من المشاركة فى هذا المشروع البحثى؟

- يمكن الحصول على مزيد من المعلومات حول هذا المشروع البحثى عن طريق الاتصال بالباحث الرئيسى على رقم التلفون أعلاه.

كما يمكن ايضا طلب الاجتماع وجها لوجه مع الباحث الرئيسى بقسم الخدمات الصيدلية بمستشفى الذرة.

هل يجب على المشاركة فى هذا المشروع البحثى؟

- لا وان الامر متروك لك تماما فى عدم المشاركة فى هذا المشروع البحثى.

كيف يتم الحفاظ على سرية المعلومات والمعاملة بها؟

لقد وضع فريق البحث اجراءات صارمة لحماية سرية وخصوصية المشاركين وهذه تشمل الاتى:-

- حفظ المعلومات الشخصية مثل الاسم والعنوان بمعزل عن بيانات المشروع الاخرى.
- لا يتم حفظ البيانات الشخصية للمشاركين فى سجلات الحاسب الالى.
- يقتصرالوصول للبيانات الشخصية للعاملين المختارين لاعضاء فريق البحث فقط.
- الاخطاء الطبية المكتشفة من خلال المشروع واسبابها ستعامل بسرية تامة ولن تؤثر فى عملك بالمستشفى.

من سيكون قادرا على استخدام هذه البيانات؟

- الوصول للمعلومات والبيانات الخاصة بهذا المشروع البحثى ستكون متاحة فقط للباحثين الذين لديهم الموافقة الاخلاقية العلمية ، وسوف يتم تحليل نتائج هذا البحث بواسطة الباحث الرئيسى كجزء من مشروع درجة الدكتوراة.

كما سيتم نشر نتائج هذا البحث فى مقالات علمية بالمجلات العالمية والمحلية دون ذكر التفاصيل الشخصية للمشاركين.

من هو الممول والمسئول عن التنظيم لهذا المشروع البحثى؟

- الباحث الرئيسى لهذا المشروع البحثى طالب فى كلية الملك فى لندن بجانب أنه صيدلى فى مستشفى الذرة ومحاضر بجامعة العلوم الطبية والتكنلوجيا.

ويتم التمويل لهذا المشروع حاليا بالموارد الذاتية وموارد حكومة السودان.

لقد تمت مراجعة هذا المشروع البحثى بواسطة لجنة مستقلة لخبراء علميين ووافقت عليه لجنة أخلاقيات المهنة بجامعة العلوم الطبية والتكنلوجيا ووفقا للوائح وزارة الصحة فى حكومة السودان.

ماذا لو سارت الامور بطريقة غير مرضية؟

a. ليس من المتصور أن هذا المشروع البحثى سوف يتسبب فى أى ضرر لاى من المشاركين فيه ،

ولمزيد من المعلومات يمكنك الاتصال ب:

علياء فيصل المهدى

تلفون 00249912162569

Appendix 3.5 CONSENT FORM FOR PATIENT SAFETY CULTURE FOCUS GROUPS – ARABIC

An exploratory study using Focus group discussion on patient safety culture

اقرار بالموافقه

أنا باحثة من جامعة العلوم الطبية والتكنلوجيا. عايزة أعرف االانظمه المتبعه للتاكد من سلامة المريض.

المسؤول من الدراسة دى هى باحثة من جامعة العلوم الطبيه والتكنلوجيا وأسمها **د. علياء فيصل**.

حنطلب منك انك تشارك فى مجموعة نقاش عن انظمة سلامة المريض.

وأهم حاجة عايزاكم تعرفوا انو البيانات حتكون سرية جدا وماحيطلع عليها زول بدون موافقتكم. الزول كان موافق يمضى هنا.....

وبعد ماشفت وقريت وفهمت الكلام ده أوافق أن اشارك فى الدراسة دى.

الاسم .....

الامضاء.....

مزيد من المعلومات الرجاء الاتصال ب:

د. علياء فيصل - جامعة العلوم الطبية والتكنلوجيا.ت 0912162569

Appendix 3.6 PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR FOCUS GROUPS ON PATIENT SAFETY CULTURE – ENGLISH

Participant Information Leaflet

An exploratory Study into patient safety culture using Manchester Patient Safety Framework

You are being invited to take part in a project that aims to explore patient safety culture at the cancer hospital. This project is part of a PhD research project but it intends to help the centre to improve its current services and improve patient care.

Before you agree to take part in this project, it is important for you to understand the purpose of this project and what it involves. Please take time to read this information carefully and take home to discuss with others.

If you have any questions, or if you wish to receive more information, please contact Alya Faysal on 00249912162569

Thank you for taking the time to consider taking part. We hope that you feel you are able to contribute. Your views are very important and will be of great help to improve chemotherapy services at the centre.

Alya Faysal Al- Mahdi

Lead Researcher

PhD Student, Kings College London

Lead Clinical Pharmacist

Radiation and Isotope Centre Khartoum

Email: alyaaalmahdi@hotmail.com

What is the purpose of this project?

The current project aims to explore patient safety culture with regards to prescribing, dispensing and administration of chemotherapy at RICK. This part of the project will explore the safeguards in place to protect patients against patient harm, the potential causes of adverse events and the feasible interventions to address when prescribing chemotherapy.

By analyzing the views of prescribers, researchers identify the potential causes of adverse events associated with chemotherapy and how to address them.

Why have I been chosen for this project?

Your name has been identified from the doctors/pharmacist list from the Pharmacy Department.

What does taking part in this project involve?

Taking part in this project involves answering questions in a focus group which will take approximately an hour. The focus group will consist of 4-6 members of the prescribing team.

What should I do if I want to take part?

If you want to take part, we ask you to sign the consent form and agree to taking part in the focus group discussion.

What should I do if I don't want to take part?

If you have decided that you don't want to contribute to this project, you are free to turn down the request verbally and not sign the consent form.

What can I do if I am unsure of taking part in this project?

More details about this project can be obtained by contacting the lead researcher on the number shown above. You can also request a face to face meeting at the pharmacy department before the focus group date.

Do I have to take part in this project?

No, it is entirely up to you if you choose not to participate in this project.

How will the information be kept confidential?

The research team has put a number of rigorous procedures in place to protect the confidentiality of participants. These include:

- Keeping information such as name and other personal details in separate files where they will not be linked to the focus group discussions.
- Not keeping a computer record of personal details of the participants.
- Access to personal data is restricted to the research team only.
- Destruction of voice recording after the analysis stage.

Who will be able to use my information?

Information from this project will be available only for researchers who have the relevant scientific ethical approval. The results will be analysed by the lead researcher as part of a PhD project.

The results of this project will be published in international and local scientific journals without mention of personal details of the participants.

Who is organizing and funding this project?

The project is led by a researcher who is a student at King's College London, a pharmacist at RICK and a lecturer at the University of Medical Sciences and Technology. It is being organized by Alya Faysal, Cate Whittlesea (King's College London) and Graham Davies (King's College London). It is currently funded by personal resources. The project has been reviewed by an independent scientific panel and approved by UMST ethics Committee in full accordance of the regulations of the Ministry of Health, government of Sudan.

What if something goes wrong?

It is not envisaged that this project will cause harm to any of the participants.

Contacts for further information

If you require any further information you can contact: Alya Faisal Al-Mahdi on: 00249912162569

Participation in this project is entirely voluntary and your response will not affect your rights in any way.

Thank you for taking the time to read this information sheet which is yours to keep.

Appendix 3.7 CONSENT FORM FOR PARTICIPATING IN FOCUS GROUPS -SAFETY CULTURE

CONSENT FORM

Focus group exercise on patient safety culture

Research Team Lead: Alya Faysal Al-Mahdi (RICK)

You are provided with two copies of this consent form; one is to be returned to the research team and the other for you to keep.

1. I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason.
3. I agree to what I say during focus group discussions and my views can only be used, anonymously, in the presentation of the research.
4. I agree to take part in the above study.

If I require a report of the results of this research project, I will contact the lead researcher by phone on 00249912162569.

……	……	……
Name of participant	Signature	Date

……	……
Name of researcher	Signature

Appendix 3.8 MAPSAF PRESENTATION SLIDES

MANCHESTER 1824 The University of Manchester — NHS National Patient Safety Agency

Self-reflecting on our safety culture

Alya Faisal Al-Mahdi

MANCHESTER 1824 The University of Manchester — NHS National Patient Safety Agency

NPSA Seven Steps to Patient Safety

Step One: Build a safety culture

A safety culture is....

- A culture where staff have a constant and active awareness of the potential for things to go wrong
- A culture that is open and fair, and one that encourages people to speak up about mistakes

MANCHESTER 1824 The University of Manchester — NHS National Patient Safety Agency

Housekeeping

- Start & Finish Times
- Fire Alarm
- Tea, coffee, lunch
- Mobiles and pagers
- Toilets
- Don't get too comfy!

MANCHESTER 1824 The University of Manchester — NHS National Patient Safety Agency

Manchester Patient Safety Framework

- Originally developed for use in primary care by Manchester University
- Based on Ron Westrum's (1993) theory of organisational safety – "organisational personality"
- Tailored from a tool developed for the oil industry and used by Shell Plc.
- Now piloted and developed for use in acute, mental health, ambulance settings

MANCHESTER 1824 The University of Manchester — NHS National Patient Safety Agency

Seven Steps to Patient Safety

1. Safety culture
2. Lead & support staff
3. Integrated risk management
4. Promote incident reporting
5. Involve patients and the public
6. Learn and share lessons
7. Implement solutions

MANCHESTER 1824 The University of Manchester — NHS National Patient Safety Agency

The theory behind the framework

Pathological

- Information is hidden
- Messengers are "shot"
- Responsibilities are shirked
- Bridging is discouraged
- Failure is covered up
- New ideas are actively crushed

Appendix 3.9 ENGLISH MAPSAF EVALUATION FORM

AN EXPLORATORY STUDY IN PATIENT SAFETY CULTURE USING THE MANCHESTER PATIENT SAFETY FRAMEWORK

MaPSaF Evaluation

Dimension of patient safety culture	A	B	C	D	E
1. Commitment to overall continuous improvement					
2. Priority given to safety					
3. System errors and individual responsibility					
4. Recording incidents and best practice					
5. Evaluating incidents and best practice					
6. Learning and effecting change					
7. Communication about safety issues					
8. Personnel management and safety issues					
9. Staff education and training					
10. Team working					

T = Team O = Organisation

Appendix 3.10 ARABIC MAPSAF EVALUATION

(MaPSaF Evaluation تقيم سلامة المرضى)

ابعاد ثقافة سلامة المرضى	A	B	C	D	E
1. **الالتزام الشامل للتقدم المستمر**					
2. **الاولوية للسلامة**					
3. أخطاء النظام والمسئوليات الفردية					
4. **تسجيل الحوادث وأفضل السبل لذلك**					
5. تقييم الحوادث والممارسة الجيدة					
6. التعلم واحداث التغير					
7. **التواصل فى مواضيع السلامة**					
8. **ادارة شئون العاملين وأمور السلامة**					
9. **تعليم وتدريب الموظفين**					
10. **العمل كفرق**					

المؤسسه -م

الفريق -ف

Appendix 4.1 Participant Information leaflet and for doctor key informant interviews

Participant Information Leaflet

Exploratory Study to identify the process used by Medical Staff to Prescribe chemotherapy

You are being invited to take part in a project that aims to identify the nature and frequency of prescribing errors at the cancer hospital. This project is part of a PhD research project but it intends to help RICK improve its current services and improve patient care.

Before you agree to take part in this project, it is important for you to understand the purpose of this project and what it involves. Please take time to read this information carefully and take home to discuss with others.

If you have any questions, or if you wish to receive more information, please contact Alya Faysal on 00249912162569

Thank you for taking the time to consider taking part. We hope that you feel you are able to contribute. Your views are very important and will be of great help to improve chemotherapy services at RICK.

Alya Faysal Al- Mahdi

Lead Researcher

PhD Student, Kings College London

Lead Clinical Pharmacist

Radiation and Isotope Centre Khartoum

Email: alyaaalmahdi@hotmail.com

What is the purpose of this project?

The current project aims to explore the nature, frequency and potential causes of medication errors. This part of the project will explore the methods used by doctors in prescribing and what steps they take to reduce medication errors.

By analyzing the views of prescribers, researchers will be able to map out the chemotherapy process and identify areas of improvement.

Why have I been chosen for this project?

Your name has been identified from the prescribing doctors list that is sent to pharmacy.

What does taking part in this project involve?

Taking part in this project involves answering questions in a face to face interview. The interview will take 30-54 minutes.

What should I do if I want to take part?

If you want to take part, we ask you to sign the consent form and agree to taking part in the interview.

What should I do if I don't want to take part?

If you have decided that you don't want to contribute to this project, you are free to turn down the request for interview verbally and not sign the consent form.

What can I do if I am unsure of taking part in this project?

More details about this project can be obtained by contacting the lead researcher on the number shown above. You can also request a face to face meeting at RICK pharmacy department before the formal interview date.

Do I have to take part in this project?

No, it is entirely up to you if you choose not to participate in this project.

How will the information be kept confidential?

The research team has put a number of rigorous procedures in place to protect the confidentiality of participants. These include:

- Keeping information such as name and other personal details in separate files where they will not be linked to the interviews.
- Not keeping a computer record of personal details of the participants.
- Access to personal data is restricted to the research team only.

Who will be able to use my information?

Information from this project will be available only for researchers who have the relevant scientific ethical approval. The results will be analysed by the lead researcher as part of a PhD project.

The results of this project will be published in international and local scientific journals without mention of personal details of the participants.

Who is organizing and funding this project?

The project is led by a researcher who is a student at King's College London, a pharmacist at RICK and a lecturer at the University of Medical Sciences and Technology. It is being organized by Alya Faysal, Cate Whittlesea (King's College London) and Graham Davies (King's College London). It is currently funded by personal resources. The project has been reviewed by an independent scientific panel and approved by UMST ethics Committee in full accordance of the regulations of the Ministry of Health, government of Sudan.

What if something goes wrong?

It is not envisaged that this project will cause harm to any of the participants.

Contacts for further information?

If you require further information, please contact: Alya Faysal Al-Mahdi

On -00249912162569

Participation in this project is entirely voluntary and your response will not affect your rights in any way.

Thank you for taking the time to read this information sheet which is yours to keep.

Appendix 4.2 Consent form for doctor key informant interviews

KING'S College LONDON

CONSENT FORM

Exploratory Study to identify the process used by Medical Staff to Prescribe chemotherapy

Research Team Lead: Alya Faysal Al-Mahdi (RICK)

You are provided with two copies of this consent form; one is to be returned to the research team and the other for you to keep.

1. I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason.
3. I agree to what I say during interviews and my views can only be used, anonymously, in the presentation of the research.
4. I agree to take part in the above study.

If I require a report of the results of this research project, I will contact the lead researcher by phone on 00249912162569.

.....	.....	.....
Name of participant	Signature	Date
.....	.....	
Name of researcher	Signature	

Appendix 4.3 Key informant interview schedule – Doctors

Interview Schedule for Mapping the Prescribing Process at a Cancer Centre

Interview Schedule

Introduction

I am Alya Al-Mahdi and I will be conducting this interview to identify the process involved in prescribing chemotherapy to patients.

Thank you for agreeing to participate in this study which aims to identify the processes used by doctors to prescribe prescriptions and how errors are managed. I would be grateful if you can give me a verbal confirmation that you have read the information sheet and that you have signed the consent form.

This interview will take 30-45 minutes during which I will be grateful if you explain to me the process you use in prescribing chemotherapy and what steps you take to avoid errors. This interview is not meant to assess the accuracy of your actions and there are no right or wrong answers to the questions below.

You have the right to withdraw from this interview at any time if you feel you don't want to continue any more. I would like to assure you that all the information, obtained in this interview will remain confidential and will only be used for research reasons. Any personal data will be anonymized during the analysis, so I will not use your proper name.

I would like you to explain things to me as if I am a new medical officer who has just joined this centre. I may ask for some clarification or examples about the issues you describe. In addition, please feel free to stop me if you have a question or clarification.

I will be taking notes during this interview, however, I will also be using a digital recorder to make sure that I capture the whole conversation. I will destroy the recorded data after completing my PhD studies. Would that be okay?

Background

I want you to give me some background information about the clinic where you work:

How is the outpatient clinic organized?

We have two clinics

How does the clinic operate?

What types of staff are involved? Number of staff and responsibility

What is your role in prescribing chemotherapy?

Describe a busy day what happens on a normal day and what happens on a busy day.

Grand Tour questions - The prescribing process

Now we would like to focus on the prescribing process. Now look at this patient file and the prescription form.

Can you describe how you use the patient file to aid prescribing?

Can you please describe the steps you take when you write the prescription?

Do you use any strategies/ references, equipment to help you prescribe appropriately?

Under what circumstances would you adopt a different process.

(prompts e.g. under the direction of a senior, when copying from the file, under the request of a patient)

Mino Tour questions - Training for prescription writing

Where you give training on how to write prescriptions? (prompts; undergraduate training, house officer training, registrar training, RICK training)

What other learning experience have you used to develop your prescription writing skills?

Have you modified your prescription writing in response to an error? Please explain further

Will you say you are more confident now to prescribe than when you first joined RICK. Explain further.

Grand Tour Questions - Prescription Errors

International studies have shown that medication errors do occur, tell me about the most common type of medication error that occurs with chemotherapy prescriptions.

In your opinion, which is the most serious error?

(prompts; overdose, patient not fit, omission errors, failure to give medicines.)

Are you aware of a prescription error that has led to patient harm? Give me an example of that.

(prompts; patient had a more severe adverse drug reaction, unexpected hospital admission, permanent disability, death)

What procedure would you follow when a medication error occurs?

What would you personally do if you had seen a prescription error?

What steps would you take if are notified of a prescription error by a patient?

Do you think there were any factors that contributed to the errors you describe? (Prompts, phone calls, interruptions, busy work environment, demanding patients/ co-patients)

Conclusion

I am very grateful for providing me with information regarding work practice at the chemotherapy clinic.

In your opinion, are there any changes needed to reduce the incidence of medication errors?

Thank you very much for making time to talk to me. If in the future, I need any more information or clarification, would I be able to contact you?

Appendix 4.4 Data Collection Tool – Prescription Details

An investigation into the frequency and nature of prescription errors -Prescription details collection form										
Prescription No	**Hospital No**	**Gender**	**Consultant team**	**Level of prescriber**	**Diagnosis**	**Drugs prescribed**	**Chemotherapy protocol**	**Position of clinic**	**Day of clinic**	**Error**

Appendix 4.5 Prescription Error Recording Form

An investigation into the nature and frequency of prescription errors- Error Recording Form			
Date: Day (Circle as appropriate) Sun Mon Tue Wed Thu	Data Collector:	Time:	Form No:

Prescription details			
Patient name: Hospital No:	Regimen:	Date prescribed:	Date presented:

Where did the prescription come from (circle): Private clinic (please state) RICK	Prescriber details- Name: Grade: JReg SReg FReg ACont JCon SCon

Type of error	Error present Please tick box or circle N/A
Wrong chemotherapy drug/regimen	□
Patient IS NOT fit to receive chemotherapy	□
Protocol INAPPROPRIATE to the disease histopathology	□
Body Surface Area INCORRECTLY calculated (EXCEPT for carboplatin)	□
Doses INCORRECTLY calculated (Check below according to protocol and where appropriate)	
INACCURATE calvert calculation for carboplatin	□
INACCURATE calculation according to BSA for other drugs than carboplatin	□
According to renal function	□
According to hepatic Function	□
cumulative / maximum dose reached	□
Prescribed an appropriate diluents/infusion	□
Prescribed an appropriate route	□
DID NOT prescribe appropriate supportive therapy (Check below according to protocol)	
Anti-emetics	□
Pre-medication for taxanes	□
Intravenous fluids	□
Electrolytes	□
Others (e.g. mesna, leucovorin, atropine, mannitol)	□
Prescribed a drug, dose or route that is not that intended	□
Writing illegibly	□
Writing a drug's name using non standard abbreviations	□
Omitting the route of administration of a drug that can be given by more than one route	□
Omission of the length of infusion	□
Transcribing a medication order incorrectly from the patient original plan	□
Write milligrams when micrograms are intended	□

Appendix 4.6 Participant Information Leaflet for Critical Incident Interviews - Doctors

Participant Information Leaflet

Exploratory Study to identify the frequency, nature and causes of prescription errors

You are being invited to take part in a project that aims to identify the nature and frequency of prescribing errors at the cancer hospital. This project is part of a PhD research project but it intends to help RICK improve its current services and improve patient care.

Before you agree to take part in this project, it is important for you to understand the purpose of this project and what it involves. Please take time to read this information carefully and take home to discuss with others.

If you have any questions, or if you wish to receive more information, please contact Alya Faysal on 00249912162569

Thank you for taking the time to consider taking part. We hope that you feel you are able to contribute. Your views are very important and will be of great help to improve chemotherapy services at RICK.

Alya Faysal Al- Mahdi

Lead Researcher

PhD Student, Kings College London

Lead Clinical Pharmacist

Radiation and Isotope Centre Khartoum

Email: alyaaalmahdi@hotmail.com

What is the purpose of this project?

The current project aims to explore the nature, frequency and potential causes of medication errors. This part of the project involves identifying prescription errors and their causes. If you are identified as a doctor who was involved in a prescription error, you will be asked to attend a critical incident interview that focuses on the causes of the error. By analysing the views of prescribers, researchers will be able to identify common causes of errors and their possible solutions

Why have I been chosen for this project?

Your name has been identified from the prescribing doctors list that is kept in the pharmacy department.

What does taking part in this project involve?

Taking part in this project involves answering questions in a face to face interview. The interview will take 30-54 minutes. The interviews will be taped using a digital recorder to allow a more comprehensive analysis of the issues discussed.

What should I do if I want to take part?

If you want to take part, we ask you to sign the consent form and agree to taking part in the interview.

What should I do if I don't want to take part?

If you have decided that you don't want to contribute to this project, you are free to turn down the request for interview verbally and not sign the consent form.

What can I do if I am unsure of taking part in this project?

More details about this project can be obtained by contacting the lead researcher on the number shown above. You can also request a face to face meeting at RICK pharmacy department before the formal interview date.

Do I have to take part in this project?

No, it is entirely up to you if you choose not to participate in this project.

How will the information be kept confidential?

The research team has put a number of rigorous procedures in place to protect the confidentiality of participants. These include:

- Keeping information such as name and other personal details in separate files where they will not be linked to the interviews.
- Not keeping a computer record of personal details of the participants.
- Access to personal data is restricted to the research team only.

Who will be able to use my information?

Information from this project will be available only for researchers who have the relevant scientific ethical approval. The results will be analysed by the lead researcher as part of a PhD project.

The results of this project will be published in international and local scientific journals without mention of personal details of the participants.

Who is organizing and funding this project?

The project is led by a researcher who is a student at King's College London, a pharmacist at RICK and a lecturer at the University of Medical Sciences and Technology. It is being organized by Alya Faysal, Cate Whittlesea (King's College London) and Graham Davies (King's College London). It is currently funded by personal resources. The project has been reviewed by an independent scientific panel and approved by UMST ethics Committee in full accordance of the regulations of the Ministry of Health, government of Sudan.

What if something goes wrong?

It is not envisaged that this project will cause harm to any of the participants.

Contacts for further information

If you require any further information, please contact: Alya Faysal Al-Mahdi on: 00249912162569

Participation in this project is entirely voluntary and your response will not affect your rights in any way.

Thank you for taking the time to read this information sheet which is yours to keep.

Appendix 4.7 Consent Form for critical incident interviews

CONSENT FORM

Exploratory Study to identify the causes of cytotoxic chemotherapy prescribing errors

Research Team Lead: Alya Faysal Al-Mahdi (RICK)

You are provided with two copies of this consent form; one is to be returned to the research team and the other for you to keep.

1. I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason.
3. I agree to what I say during interviews and my views can only be used, anonymously, in the presentation of the research.
4. I agree to take part in the above study.

If I require a report of the results of this research project, I will contact the lead researcher by phone on 00249912162569.

…… …… ……

Name of participant Signature Date

…… ……

Name of researcher Signature

Appendix 4.8 Critical Incident Interview Schedule

Interview schedule for the assessment of medication errors

My name is Alya Al-Mahdi and I am the principle researcher on a research project exploring types and causes of chemotherapy errors which is part of a PhD study based at King's College.

I am grateful for your participation in this research project. I am interested to find out what happened and how it happened and NOT that you were involved in an error. All the information provided will be treated as strictly confidential and cannot be traced to the source. Participating in this interview is entirely voluntary and you may withdraw at any point. This information will not affect your employment in this hospital.

This interview is concerning the medication incident .....which occurred on .....when you prescribed chemotherapy. I want you to describe how and why the incident occurred. I may stop you during our conversation to clarify any unclear points.

1. Explain how the error occurred.

2. Can you describe the steps you took when writing this prescription?

3. Describe the working environment when this incident occurred (prompts: busy, interruptions, distractions, patients).

4. In your opinion, which factors do you think contributed to this incident?

5. If you were to repeat this prescription, what steps would you take to prevent this error?

6. Do you have any equipment needs relating to prescribing medicines?

Thank you for taking the time to talk to me about this incident. I may want to come back to you if I need more clarification.

Appendix 4.9 Schedule for Focus Groups – Doctors

Focus Group Schedule

Potential causes and solutions to preventable adverse events associated with chemotherapy prescribing

Welcome

Good morning and welcome. Thank you for taking the time to take part in this discussion on the nature and potential causes of adverse events related to chemotherapy use. I am here today in my capacity as a researcher from King's College London working on a PhD project to identify areas which affect patient safety in the chemotherapy department

Aim of the study

As part of my PhD project, we identified areas of common prescribing adverse events and their potential causes. This discussion is to obtain your opinions and experiences with regards to issues associated with prescribing of cytotoxics in this hospital.

Confidentiality

I am interested to hear your opinions and experiences with regards to issues with prescribing chemotherapy. There are no right or wrong answers and your views will be treated as strictly confidential. The data will be anonymised during analysis and anyone outside this room will not be able to link the views expressed by the participants to this discussion. I would like to ask you to freely express your views or add comments about your experiences, however, you should not feel under pressure to say anything if you don't have a contribution. You have the right to leave this discussion at any time if you feel you don't want to continue.

Recording the discussion

I will be taking notes and using a digital recorder during this discussion to make sure that I capture all the issues you raise. I will destroy the recorded data after completing my PhD studies. My assistant Sara will be taking most of the notes and will not take part in the discussions. I would like to ask you not to talk when others are speaking so that I will be able to identify all the points raised.

Language of discussion

I will ask the questions in English and you can answer in either English or Arabic or whichever mix you are comfortable with. If you want me to repeat the question in Arabic, please ask.

Areas to be covered

The following areas will be covered during the discussion:

1. The safeguards in the system to ensure safe prescribing of chemotherapy to protect patients from harm
2. Factors contribute to prescribing errors
3. Intervention or systems which could further safeguard patients.

Just to repeat again; I am only interested to hear your views and opinions and there are no right or wrong answers.

If you have any questions at this point, I will be happy to answer them before we progress with the discussion.

Introduction

First, I am going to set the digital recorder running before we start on the introductions. I am going to distrbute a piece of paper to help me differentiate voices on the recorder. (at this point each participant will be handed a piece of paper stating: I am participant number (1,2,3,4,5,or 6) and I am consenting to this focus group discussion).

Please read what is in front of you in your normal voice.

(allow the participants to complete the exercise and thank them before staring on an indtroduction of the topic to be discussed)

There are many definitions to prescribing errors and for the sake of this research we will adopt the following definition:

A prescription error occurs when-

"as a result of a prescribing decision or prescription writing process, there is an unintentional significant:

(1) reduction in the probability of treatment being timely and effective or

(2) increase in the risk of harm when compared with generally accepted practice (Dean 2000)

The following are the common types of prescribing errors:

- Incomplete prescription
- Use of non-standard abbreviations
- Incorrect dose
- Incorrect frequency
- Illegible prescription
- Incorrect rate of infusion
- Incorrect route
- Transcription error
- Inappropriate choice of medication

(pass around a handout of a definition of the above categories)

Safeguards to protect patients against potential harm

I am going to ask you in turn to to describe for me the process that you follow when you see a patient who is due to receive a chemotherapy prescription.

What are the formal and informal safeguards to protect patients against harm in case of a prescribing error in chemotherapy?

Encourage discussion in the group and ensure the following areas are covered:

- Training and CPD
- Competency and Prescribing privilegs
- Knowledge about drug
- Evidence based medicines and protocols
- Checking dose and contraindications
- Second checks
- Meetings and grand rounds
- Patient consent
- Monitoring patients and Follow up
- Use of abbreviations
- Writing in patients records

(handy phrases: do you think?, What is your opinion on? What are your thoughts on that? How do you feel about…? what do think the impact of …….is?)

Types of prescribing errors

What are the most common types of prescribing errors in your opinion?

Are you aware of any prescribing errors that have resulted in actual patient harm?

(Encourage participants to tell stories of errors they have witnessed)

Ensure the following are covered:

- Dose errors
- Route and frequency errors
- Legibility and completeness of prescriptions
- Choice of medication
- Transcription errors or mishearing of orders

(handy phrases: have you ever been involved in? can you give me an example? What was your experience? What happened to the patient? What happened to the healthcare staff?)

Factors contributing to the occurrence of a prescribing error

Focusing exericse 1

- Bearing in mind some of the experiences some of you have described,on the piece of paper in front of you, write down the factors that you think may contribute to prescribing errors.

(Allow participants time to write this down)

- Ask participants if they have completed this exercise
- Encourage discussion among the group
- Ensure discussion covers the following points:
    - Workload
    - Interruptions
    - Patient knowledge
    - Prescriber training and knowledge
    - Availability of equipment necessary for prescribing- references, weight and height machines, calculators
    - Patient pressure
    - Work stressors
        - Work allocation within the prescribing team
        - Busy work environment
        - Job dissatisfaction
        - Burnout
        - Stress

(Write the contributory factors on a flip chart)

(Handy phrases: how do you feel about that? Tell me more…., do you think…..? what about….?)

How are prescribing errors managed?

We will now move on to management of prescribing errors.

If you were aware that either yourself or a colleague were involved in a precirbing error, what steps would you take to manage that error?

(encourage debate and discussion)

Ensure the following points are covered

- Reporting errors
- Patient management
- Learning from errors

(Encourage stories of how errors were previously managed)

(handy phrase: what would you do if……? Are you aware…..? would you….?)

Interventions that could be designed to reduce the factors contributing to prescribing errors

On a piece of paper in front of you, please write down what strategies could be developled to address the contributory factors listed on the flipchart?

(Encourage the group to debate the suggested solutions)

What other strategies could be used to improve the prescribing process?

Ensure the discussion covers the following points:

- Workload allocation
- Organisation of outpatient clinic
- Patient files
- Design of a pre-printed chemotherapy prescription
- Patient education
- Pre-clerking clinics
- Number of staff
- Staff mix

(write on the flip chart the solutions)

(handy phrases- what do you think..? what about…..? what are your thoughts on….?)

What are the high risk areas to be addressed?

(focusing exercise 2 – distribute a handout of a bar chart that displays the frequency and nature of prescribing errors as identified in the prescription review project)

Now we are going to idenfity the high risk areas of prescribing errors as identified in my research. Please examine the bar chart in front of you and tell me your opinion.

Allow the participants 10 minutes to debate and discuss

Ensure the following points are covered:

- Potential impact of prescribing error on patient outcomes
- Frequency of prescribing errors
- High risk area

(handy phrases- why do you think…..? what about…? Do you think…?)

What contributory factors are priority areas to be addressed?

What do you think are the most important factors contributing to chemothera prescribing errors in our hospital?

In your opinion what are the priority interventions?

We would now like to prioritise the likely intervention that will address these prescribing errors.

(Allow the participants 10 minutes to debate and discuss)

- Using a new sheet on the flip chart, note down the interventions suggested in the order they were mentioned during the discussion.

Get the group to prioritize the interventions in terms of clinical importance and feasibility. Ensure the following points are covered:

- Pre-printed prescriptions
- Workoad allocation
- Comptency based programs
- Support for prescribers from other staff

In high risk industries such as aviation, safety has been improved dramatically by application of a safety culture. What is your opinion on that and its possible implication in our setting?

Ensure the following points are covered:

- The high risk nature of healthcare
- Reporting and learning from errors
- Blame and accountability

(handy phrases: what is your opinion…? That's interesting, how can we develop this further? Does anyone have a different view…?, have you come across ?)

Conclusion

We are coming to a close to our discussion. Does anyone have anyhting more to say?

Thank you for your participation.

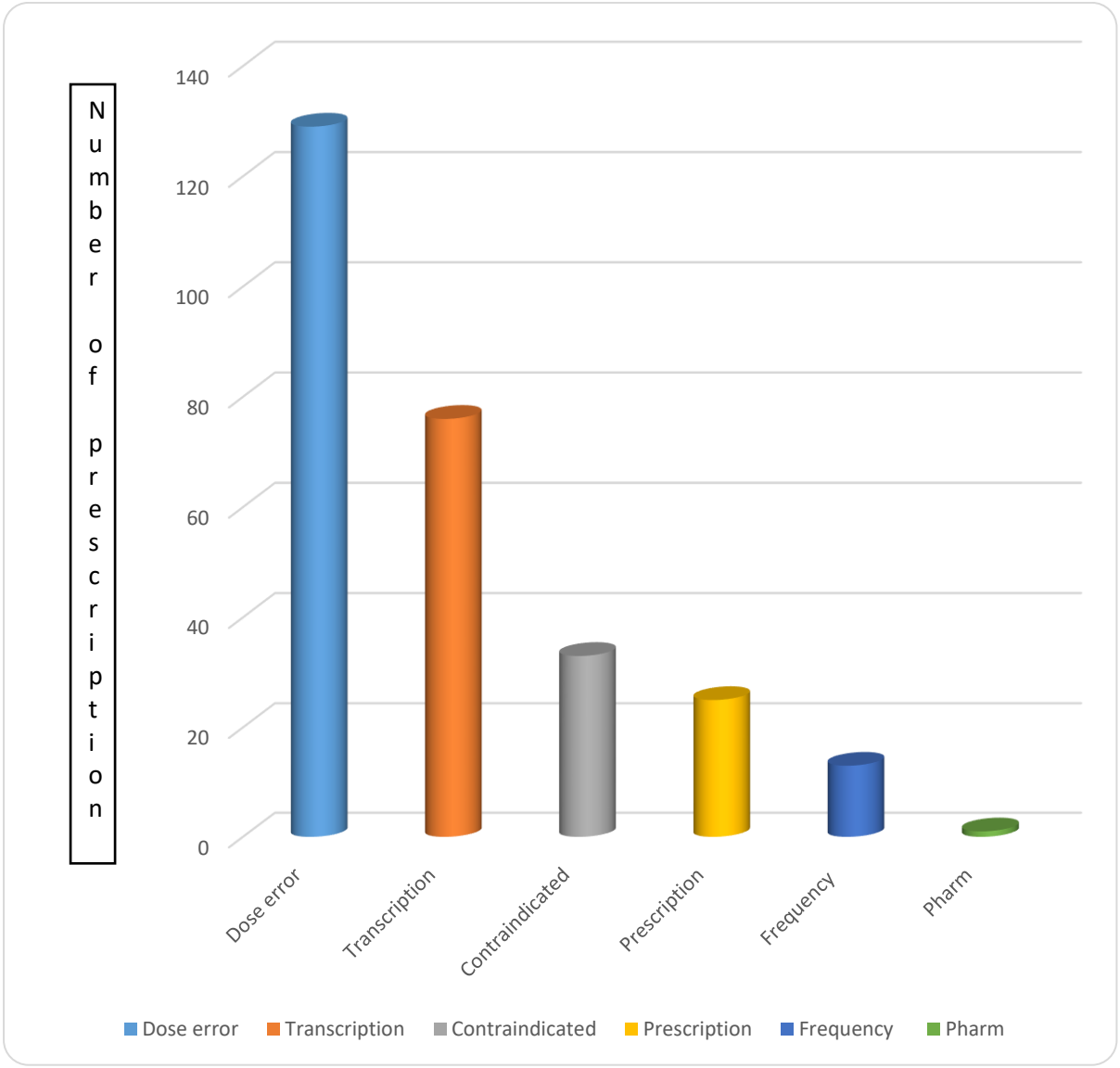
Potential causes and solutions to prescription errors associated with chemotherapy

Focus Group Exercises

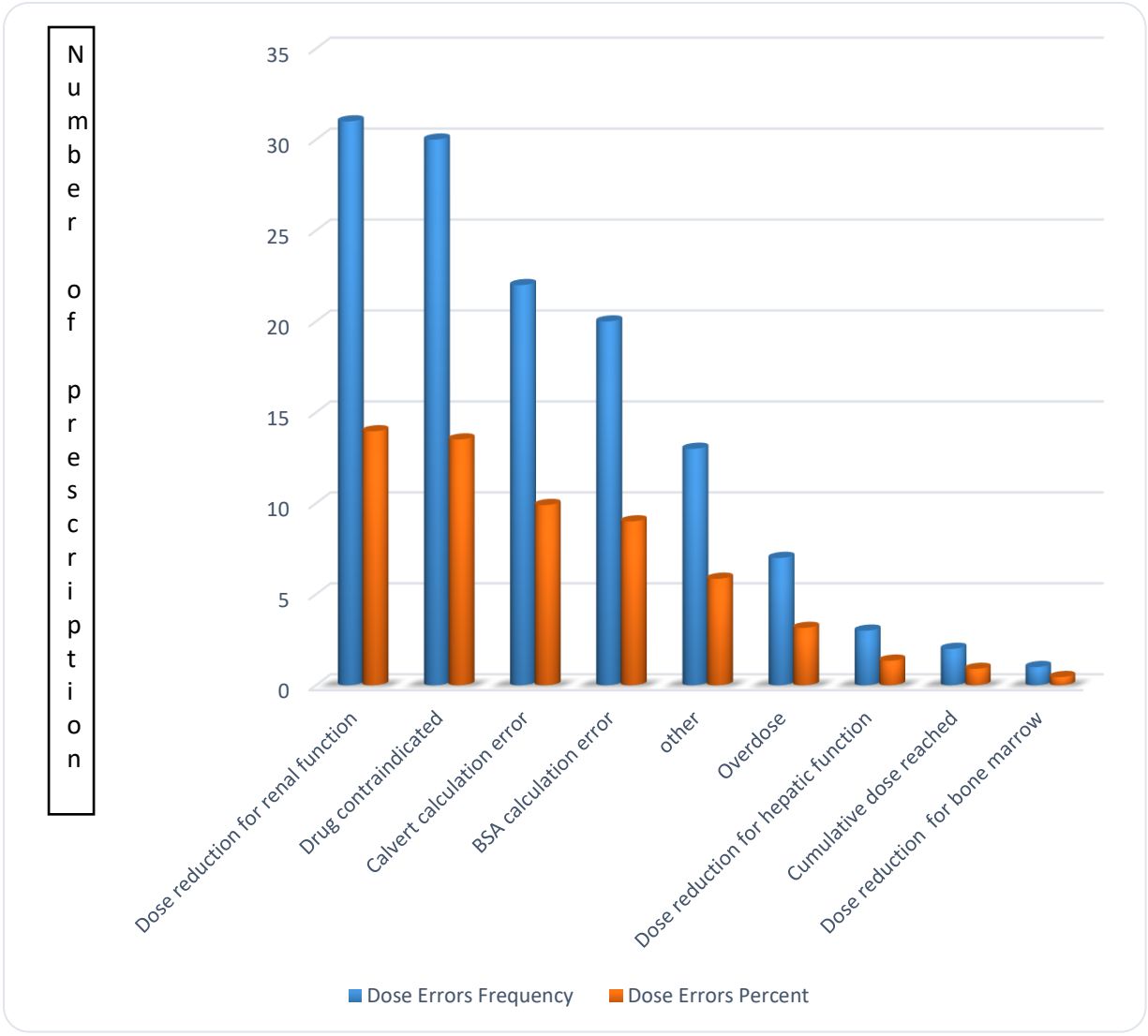
Categories of prescription errors

Category	Description
Schedule	6. Continuation of drug for a longer duration than necessary e.g. extra cycle prescribed/ Prescribing a protocol for inaccurate length of therapy 7. No indication for drug prescribed 8. Duplication of therapy/ prescribing therapy with increased frequency 9. Total cycle correct but divided into days incorrectly /Unintentional missing of a cycle
Drug contraindicated	10. Prescription of drug to which patient has significant allergy 11. Prescription of drug to which patient has clinical contra-indication such as low hematology parameters, renal failure or liver impairment 12. Continuing a drug in the event of a clinically significant adverse drug reaction 13. Prescription of drug that is contra-indicated due to drug interaction 14. Prescription of anthracyclines in a patient who has an ejection fraction less than 30%. 15. Prescription of chemotherapy when neutrophil count $<1.5x10^{6/}$/ml or haemoglobin <6g/dl or platelets $<150x10^{6}$/ml 16. Prescription of chemotherapy when ECOG performance score is>2 (Oken et al., 1982) 17. Prescription of a taxane when liver function tests: bilirubin 5x upper limit of normal or liver transaminase level >10x upper limit of normal 18. Prescription of cisplatin when renal function in below 30ml/min
Choice of drug	3. Prescription of a protocol/ drug that was not intended 4. Prescription of a protocol that is not recommended for management of the specific
Wrong dose	8. Exceeding the maximum cumulative lifetime dosage for anthracylines and similar drugs 9. Dose/rate mismatch for infusions 10. Overdose/underdose by more than 5% due to inaccurate calculation of Body Surface Area. 11. Overdose/underdose by more than 5% due to inaccurate application of Calvert equation for carboplatin 12. Overdose by more than 5% due to low renal function or increased liver test 13. Choosing a dose more/less than 5% of that specified by the chemotherapy protocol 14. Wrong dose calculation according to renal and liver function
Administration of drug	1. Wrong route 2. Wrong formulation 3. Administration times incorrect or not specified 4. Instructions for IV administration incorrect 5. Start date or days of chemotherapy incorrect or not specified
Prescription details	1. Product or formulation not specified 2. Strength or dose not specified 3. Route not specified 4. Prescription not signed 5. Prescription with missing patient name 6. Prescription with missing date 7. Drug written using inaccurate spelling or abbreviations

Frequency and nature of Prescription Errors Identified in the study



Types of dose errors



In your opinion what are the most common types of prescription errors :

……

……

……

……

……

……

……

……

……

In your opinion what are the most common contributory factors assocaited with prescription errors:

……

……

……

……

……

……

……

……

……

……

Appendix 4.11 PIL for Focus Groups on Prescribing errors

Participant Information Leaflet

Potential causes and solutions to preventable adverse events associated with chemotherapy prescribing

You are being invited to take part in a project that aims to identify the nature and frequency of adverse events associated with prescribing chemotherapy at the cancer hospital. This project is part of a PhD research project but it intends to help the centre to improve its current services and improve patient care.

Before you agree to take part in this project, it is important for you to understand the purpose of this project and what it involves. Please take time to read this information carefully and take home to discuss with others.

If you have any questions, or if you wish to receive more information, please contact Alya Faysal on 00249912162569

Thank you for taking the time to consider taking part. We hope that you feel you are able to contribute. Your views are very important and will be of great help to improve chemotherapy services at the centre.

Alya Faysal Al- Mahdi

Lead Researcher

PhD Student, Kings College London

Lead Clinical Pharmacist

Radiation and Isotope Centre Khartoum

Email: alyaaalmahdi@hotmail.com

What is the purpose of this project?

The current project aims to explore the nature, frequency and potential causes of adverse events associated with prescribing chemotherapy. This part of the project will explore the safeguards in place to protect patients against patient harm, the potential causes of adverse events and the feasible interventions to address when prescribing chemotherapy.

By analyzing the views of prescribers, researchers identify the potential causes of adverse events associated with chemotherapy and how to address them.

Why have I been chosen for this project?

Your name has been identified from the prescribing doctors list that in the Pharmacy Department.

What does taking part in this project involve?

Taking part in this project involves answering questions in a focus group discussion which will take approximately an hour. The focus group will consist of 4-6 members of the prescribing team.

What should I do if I want to take part?

If you want to take part, we ask you to sign the consent form and agree to taking part in the focus group discussion.

What should I do if I don't want to take part?

If you have decided that you don't want to contribute to this project, you are free to turn down the request verbally and not sign the consent form.

What can I do if I am unsure of taking part in this project?

More details about this project can be obtained by contacting the lead researcher on the number shown above. You can also request a face to face meeting at the pharmacy department before the focus group date.

Do I have to take part in this project?

No, it is entirely up to you if you choose not to participate in this project.

How will the information be kept confidential?

The research team has put a number of rigorous procedures in place to protect the confidentiality of participants. These include:

- Keeping information such as name and other personal details in separate files where they will not be linked to the focus group discussions.
- Not keeping a computer record of personal details of the participants.
- Access to personal data is restricted to the research team only.
- Destruction of voice recording after the analysis stage.

Who will be able to use my information?

Information from this project will be available only for researchers who have the relevant scientific ethical approval. The results will be analysed by the lead researcher as part of a PhD project.

The results of this project will be published in international and local scientific journals without mention of personal details of the participants.

Who is organizing and funding this project?

The project is led by a researcher who is a student at King's College London, a pharmacist at RICK and a lecturer at the University of Medical Sciences and Technology. It is being organized by Alya Faysal, Cate Whittlesea (King's College London) and Graham Davies (King's College London). It is currently funded by personal resources. The project has been reviewed by an independent scientific panel and approved by UMST ethics Committee in full accordance of the regulations of the Ministry of Health, government of Sudan.

What if something goes wrong?

It is not envisaged that this project will cause harm to any of the participants.

Contacts for further information

If you require any further information you can contact: Alya Faisal Al-Mahdi on: 00249912162569

Participation in this project is entirely voluntary and your response will not affect your rights in any way.

Thank you for taking the time to read this information sheet which is yours to keep.

Appendix 4.12 Doctors consent form- focus groups

CONSENT FORM

Potential causes and solutions to preventable adverse events associated with chemotherapy prescribing

Research Team Lead: Alya Faysal Al-Mahdi (RICK)

You are provided with two copies of this consent form; one is to be returned to the research team and the other for you to keep.

5. I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
6. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason.
7. I agree to what I say during focus group discussions and my views can only be used, anonymously, in the presentation of the research.
8. I agree to take part in the above study.

If I require a report of the results of this research project, I will contact the lead researcher by phone on 00249912162569.

……	……	……
Name of participant	Signature	Date

Appendix 5.1 Participant Information Leaflet for Key Informant Interviews- Nurses

Participant Information Leaflet

Exploratory Study to identify the process used by nursing staff to prepare and administer cytotoxic chemotherapy

You are being invited to take part in a project that aims to identify the nature and frequency of prescribing errors at the cancer hospital. This project is part of a PhD research project but it intends to help RICK improve its current services and improve patient care.

Before you agree to take part in this project, it is important for you to understand the purpose of this project and what it involves. Please take time to read this information carefully and take home to discuss with others.

If you have any questions, or if you wish to receive more information, please contact Alya Faysal on 00249912162569

Thank you for taking the time to consider taking part. We hope that you feel you are able to contribute. Your views are very important and will be of great help to improve chemotherapy services at RICK.

Alya Faysal Al- Mahdi

Lead Researcher

PhD Student, Kings College London

Lead Clinical Pharmacist

Radiation and Isotope Centre Khartoum

Email: alyaaalmahdi@hotmail.com

What is the purpose of this project?

The current project aims to explore the nature, frequency and potential causes of medication errors. This part of the project will explore the methods used by nurses in preparing and administering cytotoxic chemotherapy and what steps are taken to reduce errors.

By analysing the views of nurses, researchers will be able to map out the chemotherapy process and identify areas of improvement.

Why have I been chosen for this project?

Your name has been identified from the nursing staff list that are kept at human resources.

What does taking part in this project involve?

Taking part in this project involves answering questions in a face to face interview. The interview will take 30-54 minutes. The interview will be taped using a digital recorder in order to ensure comprehensive analysis of the issues raised.

What should I do if I want to take part?

If you want to take part, we ask you to sign the consent form and agree to taking part in the interview.

What should I do if I don't want to take part?

If you have decided that you don't want to contribute to this project, you are free to turn down the request for interview verbally and not sign the consent form.

What can I do if I am unsure of taking part in this project?

More details about this project can be obtained by contacting the lead researcher on the number shown above. You can also request a face to face meeting at RICK pharmacy department before the formal interview date.

Do I have to take part in this project?

No, it is entirely up to you if you choose not to participate in this project.

How will the information be kept confidential?

The research team has put a number of rigorous procedures in place to protect the confidentiality of participants. These include:

- Keeping information such as name and other personal details in separate files where they will not be linked to the interviews.
- Not keeping a computer record of personal details of the participants.
- Access to personal data is restricted to the research team only.

Who will be able to use my information?

Information from this project will be available only for researchers who have the relevant scientific ethical approval. The results will be analysed by the lead researcher as part of a PhD project.

The results of this project will be published in international and local scientific journals without mention of personal details of the participants.

Who is organizing and funding this project?

The project is led by a researcher who is a student at King's College London, a pharmacist at RICK and a lecturer at the University of Medical Sciences and Technology. It is being organized by Alya Faysal, Cate Whittlesea (King's College London) and Graham Davies (King's College London). It is currently funded by personal resources. The project has been reviewed by an independent scientific panel and approved by UMST ethics Committee in full accordance of the regulations of the Ministry of Health, government of Sudan.

What if something goes wrong?

It is not envisaged that this project will cause harm to any of the participants.

Contacts for further information

If you require any further information, please contact: Alya Faysal Al-Mahdi on: 00249912162569

Participation in this project is entirely voluntary and your response will not affect your rights in any way.

Thank you for taking the time to read this information sheet which is yours to keep.

Appendix 5.2 Consent Form for Nurses to participate in study

CONSENT FORM

Exploratory Study to identify the process used by nursing staff to prepare and administer cytotoxic chemotherapy

Research Team Lead: Alya Faysal Al-Mahdi (RICK)

You are provided with two copies of this consent form; one is to be returned to the research team and the other for you to keep.

1. I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason.
3. I agree to what I say during interviews and my views can only be used, anonymously, in the presentation of the research.
4. I agree to take part in the above study.

If I require a report of the results of this research project, I will contact the lead researcher by phone on 00249912162569.

…… …… ……

Name of participant Signature Date

…… ……

Name of researcher Signature

Appendix 5.3 Key Informant Interview Schedule – Nurses

An exploratory study about the nature frequency and causes of administration errors

Interview Schedule

Introduction

Draft interview schedule for an exploratory study to identify the work process involved in administration of chemotherapy

Introduction

I am Alya Al-Mahdi and I will be conducting this interview to identify the process involved in administration of chemotherapy to patients.

This interview will take up to about one hour during which I will be grateful if you explain to me the details of the steps taken in administration of chemotherapy and what steps you take to avoid errors. This interview is not meant to assess the accuracy of your actions and the information provided will be treated as strictly confidential.

I may ask for some clarification about the processes you describe. Please feel free to stop me if you have a question of clarification.

Background

I want you to give me some background information about the chemotherapy day ward where you work:

- The organisation of the ward
- How does the ward operate?
- What types of staff are involved?
- Describe a busy day
- Describe the patient journey when they present for chemotherapy

Grand tour questions

Now we would like to focus on the administration process.

Can you describe how a chemotherapy order is received on the day ward?

Can you describe how medications are delivered and received on the day ward?

Now please describe the stages that a medication goes through before being administered to the patient.

What steps do you take to administer the medicine to the patient?

Mini tour questions

What types of staff are involved in the medication administration process?

What happens if a medication error is detected?

Tell me about the training you were provided with before starting to make or administer chemotherapy?

Do you have any concerns when administering chemotherapy?

Grand Tour questions

International studies have shown that medication errors do occur, tell me about the most common type of medication error that occurs during the preparation and administration of chemotherapy.

In your opinion, which one would you consider serious and has anyone been exposed to harm while receiving chemotherapy?

What do you think are the contributing factors to each of the incidents you describe? (Prompts, phone calls, interruptions, busy work environment, demanding patients/ co-patients)

Conclusion

I am very grateful for providing me with information regarding work practice at the chemotherapy day ward.

Do you think that you may have any more experiences that you think are relevant to this study?

In your opinion, what changes are needed to reduce the incidence of medication errors?

Thank you very much for making time to talk to me. If in the future, I need any more information or clarification, would I be able to contact you?

Appendix 5.4 Draft Chemotherapy Administration Observation Tool

<u>Data Collection Form for observations on chemotherapy administration</u> (circle where appropriate)

Date:			
Time:		**Data collector**	
Healthcare practitioner involved:	**Matron** **Sister** **Nurse** **Doctor**		
Item prepared			
Protection from cytotoxic drug	**Wearing gloves**	**Yes**	**no**
	Wearing goggles	**Yes**	**no**
	Wearing closed toe shoes	**Yes**	**no**
	Wearing protective overcoat	**Yes**	**no**
Aseptic procedure:	**Wash hands**	**Yes**	**no**
	Clean surface of work	**Yes**	**no**
	Swab vials	**Yes**	**no**
	Removal of syringe from wrapping	**Yes**	**no**
	Using non touch technique	**Yes**	**no**
Drug calculations	**Accurate calculation**	**Yes**	**no**
	Obtain second check	**Yes**	**no**
Diluent	**Correct diluents**	**Yes**	**no**
	Volume	**Yes**	**no**
	Obtain second check	**Yes**	**no**
Removal of dose	**Correct volume**	**Yes**	**no**
	Obtain second check	**Yes**	**no**
Labeling	**Patient name**	**Yes**	**no**
	Drug name	**Yes**	**no**
	Dose	**Yes**	**no**
	Route	**Yes**	**no**
	Concentration/ final volume	**Yes**	**no**
	Time prepared	**Yes**	**no**
	Signature	**Yes**	**no**
Appearance of final product	**Checked and acceptable**	**Yes**	**no**
Drug administration	**Checked Patient name**	**Yes**	**no**

	Checked Prescription details	**Yes no**
	Checked Allergy status	**Yes no**
	Changed the giving set	**Yes no**
	Checked Venous access	**Yes no**
	Aseptic technique used at all times	**Yes no**
	Infusion rate (where applicable)	**Yes no n/a**
	Followed order of administration	**Yes no**
	If last drug- washed out the line	**Yes no n/a**
	Monitored patient	**Yes no**
	Recorded administration of drug in patient notes	**Yes no**

Appendix 5.5 Categorisation of administration errors according to NRLS

Categories of intravenous medicines error based on NRLS injectable medicines audit (2007) with definitions (NPSA, 2007a)

Medication error	Definition
Wrong dose or frequency	• The volume of medicine withdrawn doesn't correspond with the prescription. • Giving a chemotherapy medicine in discordance with the doctor's advice either giving the medicine too frequently or less frequently.
Omitted medicine or dose	The patient didn't receive a prescribed medicine even though it was supplied from the pharmacy
Mismatching medicine and patient	The medicine is prescribed correctly for one patient but given incorrectly to another
Wrong route	Giving the medicine by other than the route prescribed on the prescription
Wrong method of preparation	Preparing an injectable medicine in discordance with the manufacturer's recommendations/ hospital policy.
Wrong label	• Attaching an incorrect label to a correctly prepared injectable solution. • Attaching a correct label to an incorrectly prepared injectable solution • Not attaching a label to an injectable medicine
Other	• Adjusting the rate of infusion in discordance with hospital protocol. • Administering multiple chemotherapy medicines in the incorrect order according to hospital protocol. • Not adhering to aseptic technique. • Operator not wearing necessary protection • Disposal of chemotherapy used vials, syringes, bags and intravenous lines in bins not dedicated to chemotherapy medicines • Disposal of sharps in bins and areas other than the sharps containers

Appendix 5.6 Final Chemotherapy administration observation tool (Circle Where Appropriate)

Date:					
Time:		**Data collector**			
Healthcare practitioner involved:	**Matron Sister Nurse Doctor** **Other (please specify) …….**				
Item prepared					
Weeing Protection from cytotoxic drug	**gloves**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	goggles	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	closed toe shoes	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	protective overcoat	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Aseptic procedure:	**Wash hands**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Clean surface of work	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Swab vials	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Removal of syringe from wrapping	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Using non touch technique	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Drug calculations	**Accurate calculation**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Obtain second check	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Diluent	**Correct diluents**	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**
	Volume	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**
	Obtain second check	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Wait for drug to dissolve	**Yes no n /a**	**Yes no n /a**	**Yes no n /a**	**Yes no n /a**
Removal of dose	**Correct volume**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Obtain second check	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Labeling	**Patient name**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Drug name	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Dose	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Route	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Concentration/ final volume	**Yes no**	**Yes no**	**Yes no**	**Yes no**

	Time prepared	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Signature	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Appearance of final product	**Checked and acceptable**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Drug administration	**Checked Patient name**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Checked Prescription details	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Checked Allergy status	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Changed the giving set	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Checked Venous access	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Aseptic technique used at all times	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Infusion rate (where applicable)	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**
	Followed order of administration	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	washed out the line after the last drug	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**	**Yes no n/a**
	Monitored patient	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Recorded administration of drug in patient notes	**Yes no**	**Yes no**	**Yes no**	**Yes no**
Safe disposal	**Cytotoxic drug**	**Yes no**	**Yes no**	**Yes no**	**Yes no**
	Sharps	**Yes no**	**Yes no**	**Yes no**	**Yes no**

Appendix 5.7 Participant Information Leaflet - Observations

An investigation of the Frequency and Causes of medication errors in chemotherapy

معلومات المشروع البحثى

ماهو الغرض من هذا المشروع البحثى؟

- هذا المشروع يهدف الى معرفة الاسباب التى تؤدى لحدوث الاخطاء الدوائية.

لماذا تم اختيارك للمشاركة فى هذا المشروع البحثى؟

- لقد تم التعرف على اسمك وتم اختيارك من سجلات العاملين بالمستشفى.

ماهى الاشياء التى تنطوى على المشاركة فى هذا المشروع البحثى؟

- رصد تحركاتك فى المستشفى فور حدوث خطأ دوائى ، ستتم مقابلتك بشكل سري وخاص للتحقق من اسباب حدوث هذا الخطأ. سيتضمن تسجيل النقاش عبر مسجل رقمى وذلك لاثراء عملية البحث والتاكد من شمولية النقاط التى اثبرت اثناء االنقاش .المشاركة فى هذا المشروع البحثى اختيلرية ولن تؤثر على عملك وترقيتك فى المستشفى

ماذا أفعل اذا كنت أرغب فى المشاركة؟

- اذا كنت ترغب فى المشاركة فى هذا المشروع البحثى فما عليك الا التوقيع فى استمارة الموافقة وتسليمه لدكتوره علياء فيصل بالصيدلية.

ماذا أفعل اذا لم اكن أرغب فى المشاركة؟

- اذا كنت اتخذت قرارك بعدم المشاركة فى هذا المشروع البحثى فما عليك الا ان ترجع الاقرار من غير امضاء.

ماذا أفعل اذا لم اكن متأكدا من المشاركة فى هذا المشروع البحثى؟

- يمكن الحصول على مزيد من المعلومات حول هذا المشروع البحثى عن طريق الاتصال بالباحث الرئيسى على رقم التلفون أعلاه.

كما يمكن ايضا طلب الاجتماع وجها لوجه مع الباحث الرئيسى بقسم الخدمات الصيدلية بمستشفى الذرة.

هل يجب على المشاركة فى هذا المشروع البحثى؟

- لا وان الامر متروك لك تماما فى عدم المشاركة فى هذا المشروع البحثى.

كيف يتم الحفاظ على سرية المعلومات والمعاملة بها؟

لقد وضع فريق البحث اجراءات صارمة لحماية سرية وخصوصية المشاركين وهذه تشمل الاتى:-

- حفظ المعلومات الشخصية مثل الاسم والعنوان بمعزل عن بيانات المشروع الاخرى.
- لا يتم حفظ البيانات الشخصية للمشاركين فى سجلات الحاسب الالى.
- يقتصرالوصول للبيانات الشخصية للعاملين المختارين لاعضاء فريق البحث فقط.
- الاخطاء الطبية المكتشفة من خلال المشروع واسبابها ستعامل بسرية تامة ولن تؤثر فى عملك بالمستشفى.

من سيكون قادرا على استخدام هذه البيانات؟

- الوصول للمعلومات والبيانات الخاصة بهذا المشروع البحثى ستكون متاحة فقط للباحثين الذين لديهم الموافقة الاخلاقية العلمية ، وسوف يتم تحليل نتائج هذا البحث بواسطة الباحث الرئيسى كجزء من مشروع درجة الدكتوراة.

كما سيتم نشر نتائج هذا البحث فى مقالات علمية بالمجلات العالمية والمحلية دون ذكر التفاصيل الشخصية للمشاركين.

من هو الممول والمسئول عن التنظيم لهذا المشروع البحثى؟

- الباحث الرئيسى لهذا المشروع البحثى طالب فى كلية الملك فى لندن بجانب أنه صيدلى فى مستشفى الذرة ومحاضر بجامعة العلوم الطبية والتكنلوجيا.

ويتم التمويل لهذا المشروع حاليا بالموارد الذاتية وموارد حكومة السودان.

لقد تمت مراجعة هذا المشروع البحثى بواسطة لجنة مستقلة لخبراء علميين ووافقت عليه لجنة أخلاقيات المهنة بجامعة العلوم الطبية والتكنلوجيا ووفقا للوائح وزارة الصحة فى حكومة السودان.

ماذا لو سارت الامور بطريقة غير مرضية؟

b. ليس من المتصور أن هذا المشروع البحثى سوف يتسبب فى أى ضرر لاى من المشاركين فيه ،

ولمزيد من المعلومات يمكنك الاتصال ب:

علياء فيصل المهدى

تلفون 00249912162569

Appendix 5.8 **Consent form for observations _ Arabic**

An investigation of the Frequency and Causes of administration and preparation errors associated with chemotherapy

اقرار بالموافقه

أنا باحثة من جامعة العلوم الطبية والتكنلوجيا. عايزة أعرف اسباب الاخطاء الدوائيه.

المسؤول من الدراسة دى هى باحثة من جامعة العلوم الطبيه والتكنلوجيا وأسمها **د. علياء فيصل**.

حنطلب منك انك تجاوب على اسئلة.

وأهم حاجة عايزاكم تعرفوا انو البيانات حتكون سرية جدا وماحيطلع عليها زول بدون موافقتكم. الزول كان موافق يمضى هنا.....

وبعد ماشفت وقريت وفهمت الكلام ده أوافق أن اشارك فى الدراسة دى.
الاسم .....
الامضاء.....

لمزيد من المعلومات الرجاء الاتصال ب:
د. علياء فيصل - جامعة العلوم الطبية والتكنلوجيا.
ت 0912162569

Appendix 5.9 Critical Incident Interview Schedule on Administration Errors

Interview schedule for the assessment of causes of chemotherapy administration errors

My name is Alya Al-Mahdi and I am the principle researcher on a research project exploring types and causes of chemotherapy errors and is part of a PhD study based at King's College.

I am grateful for your participation in this research project. I am interested to find out what happened and how it happened and NOT that you were involved in an error. All the information provided will be treated as strictly confidential and cannot be traced to the source. Participating in this interview is entirely voluntary and you may withdraw at any point. This information will not affect your employment in this hospital.

This interview is concerning the medication incident .....which occurred on .....when you were administering chemotherapy. I want you to describe how and why the incident occurred. I may stop you during our conversation to clarify any unclear point.

1. Describe the working environment when this incident occurred (prompts: busy, interruptions, distractions, patients).

2. In your opinion, which factors do you think contributed to this incident?

3. Can you describe the steps you took when you were preparing/ administering the medicine?

4. Explain how the error occurred.

5. If you were to repeat this prescription, what steps would you take to prevent this error?

6. Do you have any needs relating to administration of medicines (prompts, training, equipment, staff)?

Thank you for taking the time to talk to me about this incident. I may want to come back to you if I need more clarification.